

the medical record indicates. Rule 4(c) Report, dated December 1, 2022 (ECF No. 20) (“Mot.”).³ I later informed Petitioner that although I doubted that my concerns about the claim’s viability could be overcome, I would allow her the opportunity to set forth arguments against dismissal, and she has done so. Petitioner’s Opposition, dated September 29, 2023 (ECF No. 40) (“Opp.”). Now, for the reasons stated below, I grant Respondent’s motion to dismiss.

I. Factual Background

Petitioner’s prior medical history was significant for anemia, gastroesophageal reflux disorder, epigastric pain, and gastric bypass surgery. Ex. 6 at 32; *see also* Exs. 10 and 16. Of note, she was briefly hospitalized in January 2017 for fatigue and dizziness, which was attributed to her anemia. See Ex. 10 at 182–255. And a year prior to vaccination, she received treatment for reported pain to the touch on the left side of the head. Ex. 16 at 8. However, there is no record evidence of any pre-vaccination neurologic events, or imaging relevant to her symptoms.

Vaccination and October 2019 Hospitalization

On September 25, 2019, Petitioner (who was 53 at the time) received the flu vaccine at an appointment with Linke Ma, M.D., her primary care provider (“PCP”). Ex. 3 at 2. She was also at this time treated for iron deficiency anemia and vitamin D deficiency. *Id.*

Almost three weeks later, on October 13, 2019, Petitioner saw Munif Hussain, D.O., now complaining of paresthesia and tingling in both legs that began seven days prior (meaning October 6, 2019—eleven days after vaccination) and that was lasting all day. Ex. 4 at 5. She also reported that she did not feel the sensation of urinating at times and had difficulty sensing her rectum when wiping. *Id.* at 5–6. She denied back pain, fever, headache, weakness, recent trauma or illness, or abdominal pain, however. *Id.* at 5. On examination, Petitioner displayed decreased sensation below her knees and lower back, as well as decreased strength in both lower legs, although reflexes were present and normal. *Id.* at 5–6. Dr. Hussain sent her to an emergency department (“ED”) for additional evaluation. *Id.* at 6.

That same day, Ms. Stewart-Robinson went to the Brooklyn Hospital Center. Ex. 5 at 12. She informed emergency care treaters that she had for three days (meaning since October 10, 2019) been experiencing bilateral numbness from the waist down, plus chills, difficulty walking, neck pain, and pain in her legs that she rated five out of ten. *Id.* at 2, 12. She also identified the vaccination as when she had started to experience changes in how she felt, noting specifically that in the three prior days she had felt ascending changes in sensation in her lower extremities that

³ Filed concurrently with the Rule 4(c) Report was Respondent’s Motion to Dismiss—but the latter is a one-page document that contains no specific arguments separate from the Rule 4(c) Report. I therefore treat the Rule 4(c) Report herein as Respondent’s actual “motion,” since it sets forth the substantive grounds offered for dismissal.

progressed to numbness. *Id.* at 12. Consistent with her examination by Dr. Hussain, examination at the ED revealed decreased sensation in Petitioner’s lower extremities, but normal sensation to her abdomen, back, face, and upper extremities. *Id.* at 12–13. She also denied pain and difficulty walking, but admitted to difficulty sensing the position of her feet. *Id.* at 14.

Petitioner remained hospitalized until October 20, 2019. Ex. 5 at 32. MRIs performed of the cervical spine in this timeframe initially showed no evidence of MS, but did reveal a mild T2 prolongation measuring six by five by two-and-a-half millimeters at the base of the odontoid process, a second slight T2 prolongation measuring four millimeters at the mid-C3 level, and a third slight T2 prolongation in the lower cervical and upper thoracic cord—all of which were thought suggestive of the presence of a mild demyelinating disorder (although only the prolongation seen at C1-C2 showed enhancement—meaning it was likely a newer/active lesion).⁴ *Id.* at 108, 217. Thoracic spine MRIs taken the same dates showed prolongations at T1-T2 and T3-T4 and an approximately 23-millimeter protrusion at T3-T4, none of which showed enhancement. *Id.* at 108, 218. A CT of petitioner’s head showed no evidence of infarction, however, and a later MRI of the brain showed no abnormal enhancement. *Id.* at 124, 189, 219, 280. And Cerebrospinal fluid testing was negative for oligoclonal bands, an MS biomarker. *Id.* at 427. Petitioner’s discharge diagnosis was bilateral lower extremity weakness. *Id.* at 33.

After discharge, Ms. Stewart-Robinson went back to see Dr. Ma on October 23, 2019. Ex. 6 at 25. By this time, she was still experiencing bilateral extremity weakness and an unsteady gait, as well as numbness in the lower extremities and pelvic area ataxia. *Id.* On examination, however, she had full strength in all extremities, and pulses in all extremities were within normal limits. *Id.* at 26. Dr. Ma increased Petitioner’s neuropathic pain medication and advised her to follow up with a neurologist plus engage in physical therapy. *Id.* That same day (during a call with Dr. Ma), Petitioner confirmed she had received a TM diagnosis after hospitalization, and expressed the concern that her September vaccination had been causal. *Id.* at 28. Dr. Ma did not comment on the accuracy of that concern, but instead proposed consultation with a neurologist. *Id.*

Suspicion of MS (and Later Confirmation of Diagnosis)

On October 25, 2019, Petitioner saw neurologist Eliz Agopian, M.D., at which time she reported the symptoms of lower extremity numbness and tingling that had resulted in her prior hospitalization. Ex. 7 at 4. The numbness had now ascended to her lower torso, although she denied bowel or bladder incontinence and was not experiencing leg or upper body weakness. *Id.* On examination, Ms. Stewart-Robinson displayed sensory loss at C2-C3 areas and impaired balance, but her muscle strength was intact and her deep tendon reflexes were all rated at 2+. *Id.* at 6. Dr.

⁴ In an MS patient, imaging enhancement typically reveals the presence of new lesions (as opposed to old lesions which are considered “non-enhancing”). See *Taylor v. Sec’y of Health & Human Servs.*, No. 13-700V, 2018 WL 2050857, at * 21 & n. 4 (Fed. Cl. Spec. Mstr. Mar. 9, 2018).

Agopian reviewed prior imaging showing an enhancing lesion in the high cervical region but deemed the etiology of the lesion unclear, and proposed Petitioner be tested immediately to evaluate whether a vascular/infarction issue could be explanatory. *Id.*

To that end, Petitioner returned to the ED later that day. Ex. 10 at 521. Her ED treatment provider noted Petitioner's complaint of bilateral paresthesia for the prior four weeks (placing onset on or around September 27, 2019—two days after vaccination), but later also observed that Petitioner reported she had been experiencing a fluctuating “tightness/pulling sensation below the waist” for approximately *six months* (which, if accurate, would place onset on or about April 25, 2019—well *prior* to vaccination). *Id.* The provider also reported that Petitioner had already been evaluated for “MS among other neuro diseases.” *Id.* Petitioner declined to have another lumbar puncture and declined medication until she could see a neurologist. *Id.* at 523.

Petitioner saw a second neurologist (Adina Alport, M.D.) at New York Presbyterian Brooklyn Methodist Hospital a few days later, and complained of a tightening sensation from her belly button on down, along with numbness in her legs and genitals. Ex. 8 at 3. Her balance was poor, and she required assistance with ambulation. *Id.* at 3, 7. Exam revealed normal muscle strength and tone but reduced sensation below the knees in both legs. *Id.* at 6–7. Dr. Alport specifically notes in the record from this visit that although Petitioner's working diagnosis was TM of unknown etiology, MS or another central nervous system (“CNS”) demyelinating disease, neuromyelitis optica (“NMO”), could not be ruled out. *Id.* at 8.

In early November, Petitioner underwent more spinal cord and brain imaging. A November 1, 2019 MRI of her thoracic spine showed a few hyperintense lesions located at the T3-T4, T8, and T9-T10 levels, with the T9-T10 lesion exhibiting enhancement. Ex. 8 at 9. In addition, a November 4, 2019 MRI of the cervical spine and brain showed approximately ten foci of signal change on the brain, the largest of which was suggestive of underlying demyelination (although no brain lesions appeared enhancing), plus some intramedullary lesions on the lower cervical spine which appeared demyelinating in nature. *Id.* at 18.

Petitioner returned to New York Presbyterian Brooklyn Methodist Hospital neurology on November 4, 2019, where she reported to certified physician's assistant Melissa Velez that she continued to experience numbness and tingling in her legs, plus some urinary complaints. Ex. 8 at 11. PA-C Velez noted that the imaging supported an MS diagnosis, though lumbar puncture results would be needed to confirm it. *Id.* at 15. Later that month, Petitioner attended several physical therapy appointments, and received Solumedrol (a glucocorticoid used to treat chronic inflammatory conditions, including MS)⁵ infusions as well. Ex. 15 at 2–14; Ex. 9 at 14.

⁵ See SOLU-MEDROL® (methylprednisolone sodium succinate for injection, USP), <https://labeling.pfizer.com/showlabeling.aspx?id=648#:~:text=SOLU%2DMEDROL%20Sterile%20Powder%20is,%2C%20odorless%20hygroscopic%2C%20amorphous%20solid.> (last accessed March 31, 2024)

Petitioner reported to PA-C Velez feeling a bit better after these treatments. Ex. 8 at 23. PA-C Velez later diagnosed Petitioner with a demyelinating disorder, possibly MS, although other rheumatological or autoimmune disorders could not be eliminated, and a repeat lumbar puncture was deemed necessary. *Id.* at 27. The lumbar puncture was performed on December 3, 2019, and cerebrospinal fluid collected at this time showed greater than five oligoclonal bands (clinical evidence supporting an MS diagnosis).⁶ Ex. 10 at 39–40.

On December 12, 2019, Petitioner returned to her PCP, Dr. Ma. Ex. 6 at 20. She now reported that although her symptoms had improved, she continued to experience numbness in both feet, especially at night (with foot numbness the only issue revealed on exam). *Id.* at 20, 21. Dr. Ma noted that the etiology of her prior TM remained unknown, but could be related to an infection—or could suggest new-onset MS. *Id.* at 20. Petitioner also that month began a new round of physical therapy, informing the therapist that her symptoms had begun suddenly in October 2019 “after receiving a flu shot,” but that she had since been diagnosed with MS. *Id.* She indicated that her symptoms had now been diagnosed as MS. *Id.* She attended seven physical therapy sessions through March 13, 2020. Ex. 11 at 1–18.

Treatment in 2020 and Beyond

The medical records filed in this case establishing treatment received by Petitioner in 2020 to the present date confirm the propriety of the MS diagnosis—but do not reflect any findings that would make vaccine causation more, or less, likely.

In early January 2020, Petitioner again saw PA-C Velez and complained of worsening foot numbness, gait issues, tingling, and some urinary frequency issues. Ex. 8 at 35, 39. Testing for NMO had been negative, but prior lumbar puncture results showed greater than five oligoclonal bands and an IgG index of 1.5, which PA-C Velez characterized as “highly suggestive of MS.” *Id.* at 39. PA-C Velez at this point formally included MS in her differential diagnosis (and did not mention TM), and it was agreed that Petitioner should begin a course of medication specific to treating MS. *Id.* at 39–40. By the spring, Petitioner’s symptoms had improved somewhat, although she continued to experience numbness and burning in her feet. *Id.* at 42. PA-C Velez deemed Petitioner’s MS to be “clinically stable” at this time. *Id.* at 47.

Nevertheless, Petitioner’s symptoms and sequelae did not fully abate as time passed (more consistent with relapsing/remitting MS, rather than a monophasic, CNS demyelinating condition). In July 2020, Dr. Ma noted that Petitioner was best understood to have “MS of unknown etiology.” Ex. 6 at 13. The same view was expressed by a physical therapist who saw Petitioner that month

⁶ See *Samuels v. Sec’y of Health & Hum. Servs.*, No. 17-071V, 2020 WL 2954953 (Fed. Cl. Spec. Mstr. May 1, 2020) (experts agreeing that oligoclonal bands confirm the presence of MS).

for home care. Ex. 12 at 13–25. And Petitioner informed PA-C Velez (at a July 20, 2020 visit) that she continued to experience stiffness in the lower extremities and numbness and burning in the bilateral feet—consistent with earlier that year. Ex. 8 at 56. PA-C Velez recommended repeat MRIs of the brain and cervical spine. *Id.* at 61.

In September 2020, Ms. Stewart-Robinson returned to Dr. Ma, reporting some improvement but that she was still experiencing ongoing numbness in both feet. Ex. 6 at 5. Later that month, however, she began to feel some intermittent arm and head pain. *Id.* at 4. On September 23, 2020, she again saw PA-C Velez, after the pain became sharper and was associated with headaches. Ex. 8 at 63. She also noticed stiffness in her legs, especially in the morning, and numbness and burning in her feet. *Id.* The same issues lingered on into October, coupled with gait/balance improvements. Ex. 13 at 4. A brain MRI performed in this time period showed no significant interval change in petitioner’s white matter lesions. *Id.* at 61–62.

The remaining medical records filed in this case (for treatment received through the middle of 2021) reveal ongoing, intermittent symptoms consistent with Petitioner’s experience in 2019–20, with her receipt of the same treatments, plus additional PT, she underwent before. No records undermine the MS diagnosis, however, nor do they reflect treater thinking on an association between Petitioner’s medical issues and her receipt of the flu vaccine.

II. Procedural History

This case was initiated in April 2022, and at that time Petitioner was represented by different counsel. After the case was assigned to me, I held a status conference—and informed Petitioner right away that my prior experience with comparable cases suggested that a Vaccine Act claim that the flu vaccine can cause MS was unlikely to succeed. *See* Scheduling Order, dated July 28, 2022 (ECF No. 16). I therefore instructed Respondent to consider seeking dismissal of the claim after medical review and the filing of the Rule 4(c) Report.

As noted above, Respondent moved for dismissal concurrently with the filing of his Rule 4(c) Report, both of which were submitted in December 2022. Thereafter, prior counsel withdrew from the case, and for a period of time it was a *pro se* matter until present counsel appeared in June 2023 (ECF No. 36). After holding a status conference, I reset the deadline for Petitioner’s response to the pending motion to dismiss, and Petitioner filed her brief at the end of September 2023. The matter is now ripe for resolution.

III. Parties’ Arguments

Respondent maintains that the medical record overall best supports MS as the proper diagnosis, not TM (which can be the first sign of MS). Mot. at 15. Even though treaters may have

initially viewed Petitioner’s presenting symptoms as consistent with TM, over time they embraced MS as the diagnosis—and the testing results (MRIs, lumbar punctures) plus other clinical findings are consistent with that diagnosis. *Id.* at 15–16. Furthermore (and relying somewhat on my own pronouncements made in the course of this case), Respondent contends that vaccine causation of MS is not preponderantly-established—as well as that the record itself does not support a finding the flu vaccine was likely causal of Petitioner’s MS. *Id.* at 16–17. As a result, a causation-in-fact claim is not tenable, and the matter warrants dismissal.

Petitioner has offered a brief opposing dismissal. In summarizing the medical record, she focuses heavily on her initial presentation in October 2019, and the extent to which it was not *at that time* consistent with MS (even if later clinical and testing evidence is wholly consistent with it). *See Opp.* at 3–6. Otherwise, she explains that she was “initially diagnosed with TM and subsequently developed MS.” *Id.* at 8. TM is thus the injury she seeks to allege, and she maintains it cannot be reasonably conflated with her “ultimate MS diagnosis.” *Id.* at 16. TM. She maintains, is not only a distinct injury, but it understood to be separate even when a person suffering TM is later diagnosed with MS. *Id.* at 17.⁷

Based on this evidentiary construction, Petitioner reasons that her TM can be distinguished from her MS. At worst, it only increased her risk to develop MS—it was not an initial manifestation of it. *Opp.* at 15. She thus argues that she can meet the causation requirements to prove flu vaccine-caused TM, laying out how she has done so.⁸ *Id.* at 15, 18–22. Otherwise, Petitioner maintains “she need not prove a separate theory for causation for influenza vaccines and MS.” *Id.* at 18. And she argues that it is unfair to deny Petitioner the opportunity to offer expert testimony in support of her claim. *Id.* at 23.

⁷ Petitioner cites the National Multiple Sclerosis Society’s information page on TM, which states that “[i]n some people, transverse myelitis is the first symptom of an immune-mediated disease such as MS or NMOSD. Many individuals who have TM do not go on to develop MS.” *Transverse Myelitis (TM) and Multiple Sclerosis*, National Multiple Sclerosis Society, <https://www.nationalmssociety.org/What-is-MS/Related-Conditions/Transverse-Myelitis> (last accessed March 13, 2024).

⁸ Petitioner also contends at one point that an evidentiary standard of mere plausibility controls evaluation of the first causation prong. *Opp.* at 13. This argument is, however, contrary to the majority of Federal Circuit cases, and relies on a single recent Court of Federal Claims decision, and it has not been since embraced by numerous other Court decisions. *See Howard v. Sec’y of Health & Hum. Servs.*, 2023 WL 4117370, at *4 (Fed. Cl. May 18, 2023) (“[t]he standard has been preponderance for nearly four decades”), *appeal docketed*, No. 23-1816 (Fed. Cir. Apr. 28, 2023). And in any event, the case does not turn on whether it is merely plausible that TM is vaccine-caused, but instead whether TM is the preponderantly-supported characterization of her injury.

IV. Applicable Law

A. *Standards for Vaccine Claims*

To receive compensation in the Vaccine Program, a petitioner must prove either: (1) that he suffered a “Table Injury”—i.e., an injury falling within the Vaccine Injury Table—corresponding to one of the vaccinations in question within a statutorily prescribed period of time or, in the alternative, (2) that his illnesses were actually caused by a vaccine (a “Non-Table Injury”). See Sections 13(a)(1)(A), 11(c)(1), and 14(a), as amended by 42 C.F.R. § 100.3; § 11(c)(1)(C)(ii)(I); see also *Moberly v. Sec’y of Health & Hum. Servs.*, 592 F.3d 1315, 1321 (Fed. Cir. 2010); *Capizzano v. Sec’y of Health & Hum. Servs.*, 440 F.3d 1317, 1320 (Fed. Cir. 2006).⁹ There is no Table claim available involving the flu vaccine and either TM or MS.

For both Table and Non-Table claims, Vaccine Program petitioners bear a “preponderance of the evidence” burden of proof. Section 13(1)(a). That is, a petitioner must offer evidence that leads the “trier of fact to believe that the existence of a fact is more probable than its nonexistence before [he] may find in favor of the party who has the burden to persuade the judge of the fact’s existence.” *Moberly*, 592 F.3d at 1322 n.2; see also *Snowbank Enter. v. United States*, 6 Cl. Ct. 476, 486 (1984) (mere conjecture or speculation is insufficient under a preponderance standard). Proof of medical certainty is not required. *Bunting v. Sec’y of Health & Hum. Servs.*, 931 F.2d 867, 873 (Fed. Cir. 1991). In particular, a petitioner must demonstrate 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)); *Pafford v. Sec’y of Health & Hum. Servs.*, 451 F.3d 1352, 1355 (Fed. Cir. 2006). A petitioner may not receive a Vaccine Program award based solely on his assertions; rather, the petition must be supported by either medical records or by the opinion of a competent physician. Section 13(a)(1).

In attempting to establish entitlement to a Vaccine Program award of compensation for a Non-Table claim, a petitioner must satisfy all three of the elements established by the Federal Circuit in *Althen v. Sec’y of Health & Hum. Servs.*, 418 F.3d 1274, 1278 (Fed. Cir. 2005): “(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 proximate temporal relationship between vaccination and injury.”

Each of the *Althen* prongs requires a different showing. Under *Althen* prong one, petitioners must provide a “reputable medical theory,” demonstrating that the vaccine received *can cause* the

⁹ Decisions of special masters (some of which I reference in this ruling) constitute persuasive but not binding authority. *Hanlon v. Sec’y of Health & Hum. Servs.*, 40 Fed. Cl. 625, 630 (1998). By contrast, Federal Circuit rulings concerning legal issues are binding on special masters. *Guillory v. Sec’y of Health & Hum. Servs.*, 59 Fed. Cl. 121, 124 (2003), *aff’d* 104 F. Appx. 712 (Fed. Cir. 2004); see also *Spooner v. Sec’y of Health & Hum. Servs.*, No. 13-159V, 2014 WL 504728, at *7 n.12 (Fed. Cl. Spec. Mstr. Jan. 16, 2014).

type of injury alleged. *Pafford*, 451 F.3d at 1355–56 (citations omitted). To satisfy this prong, a petitioner’s theory must be based on a “sound and reliable medical or scientific explanation.” *Knudsen v. Sec’y of Health & Hum. Servs.*, 35 F.3d 543, 548 (Fed. Cir. 1994). Such a theory must only be “legally probable, not medically or scientifically certain.” *Knudsen*, 35 F.3d at 549.

Petitioners may satisfy the first *Althen* prong without resort to medical literature, epidemiological studies, demonstration of a specific mechanism, or a generally accepted medical theory. *Andreu v. Sec’y of Health & Hum. Servs.*, 569 F.3d 1367, 1378–79 (Fed. Cir. 2009) (citing *Capizzano*, 440 F.3d at 1325–26). Special masters, despite their expertise, are not empowered by statute to conclusively resolve what are essentially thorny scientific and medical questions, and thus scientific evidence offered to establish *Althen* prong one is viewed “not through the lens of the laboratorian, but instead from the vantage point of the Vaccine Act’s preponderant evidence standard.” *Id.* at 1380. Accordingly, special masters must take care not to increase the burden placed on petitioners in offering a scientific theory linking vaccine to injury. *Contreras*, 121 Fed. Cl. at 245.

In discussing the evidentiary standard applicable to the first *Althen* prong, the Federal Circuit has consistently rejected the contention that it can be satisfied merely by establishing the proposed causal theory’s scientific or medical *plausibility*. See *Boatmon v. Sec’y of Health & Hum. Servs.*, 941 F.3d 1351, 1359 (Fed. Cir. 2019); *LaLonde v. Sec’y of Health & Hum. Servs.*, 746 F.3d 1334, 1339 (Fed. Cir. 2014) (“[h]owever, in the past we have made clear that simply identifying a ‘plausible’ theory of causation is insufficient for a petitioner to meet her burden of proof” (citing *Moberly*, 592 F.3d at 1322)); see also *Howard v. Sec’y of Health & Hum. Servs.*, 2023 WL 4117370, at *4 (Fed. Cl. May 18, 2023) (“[t]he standard has been preponderance for nearly four decades”), *appeal docketed*, No. 23-1816 (Fed. Cir. Apr. 28, 2023). And petitioners always have the ultimate burden of establishing their *overall* Vaccine Act claim with preponderant evidence. *W.C. v. Sec’y of Health & Hum. Servs.*, 704 F.3d 1352, 1356 (Fed. Cir. 2013) (citations omitted); *Tarsell v. United States*, 133 Fed. Cl. 782, 793 (2017) (noting that *Moberly* “addresses the petitioner’s overall burden of proving causation-in-fact under the Vaccine Act” by a preponderance standard).

The second *Althen* prong requires proof of a logical sequence of cause and effect, usually supported by facts derived from a petitioner’s medical records. *Althen*, 418 F.3d at 1278; *Andreu*, 569 F.3d at 1375–77; *Capizzano*, 440 F.3d at 1326; *Grant v. Sec’y of Health & Hum. Servs.*, 956 F.2d 1144, 1148 (Fed. Cir. 1992). In establishing that a vaccine “did cause” injury, the opinions and views of the injured party’s treating physicians are entitled to some weight. *Andreu*, 569 F.3d at 1367; *Capizzano*, 440 F.3d at 1326 (“medical 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 particularly

trustworthy evidence, since they are created contemporaneously with the treatment of the patient. *Cucuras v. Sec’y of Health & Hum. Servs.*, 993 F.2d 1525, 1528 (Fed. Cir. 1993).

Medical records and statements of a treating physician, however, do not *per se* bind the special master to adopt the conclusions of such an individual, even if they must be considered and carefully evaluated. Section 13(b)(1) (providing that “[a]ny such diagnosis, conclusion, judgment, test result, report, or summary shall not be binding on the special master or court”); *Snyder v. Sec’y of Health & Hum. Servs.*, 88 Fed. Cl. 706, 746 n.67 (2009) (“there is nothing . . . that mandates that the testimony of a treating physician is sacrosanct—that it must be accepted in its entirety and cannot be rebutted”). As with expert testimony offered to establish a theory of causation, the opinions or diagnoses of treating physicians are only as trustworthy as the reasonableness of their suppositions or bases. The views of treating physicians should be weighed against other, contrary evidence also present in the record—including conflicting opinions among such individuals. *Hibbard v. Sec’y of Health & Hum. Servs.*, 100 Fed. Cl. 742, 749 (2011) (not arbitrary or capricious for special master to weigh competing treating physicians’ conclusions against each other), *aff’d*, 698 F.3d 1355 (Fed. Cir. 2012); *Veryzer v. Sec’y of Dept. of Health & Hum. Servs.*, No. 06-522V, 2011 WL 1935813, at *17 (Fed. Cl. Spec. Mstr. Apr. 29, 2011), *mot. for review denied*, 100 Fed. Cl. 344, 356 (2011), *aff’d without opinion*, 475 F. Appx. 765 (Fed. Cir. 2012).

The third *Althen* prong requires establishing a “proximate temporal relationship” between the vaccination and the injury alleged. *Althen*, 418 F.3d at 1281. That term has been equated to the phrase “medically-acceptable temporal relationship.” *Id.* A petitioner must offer “preponderant proof that the onset of symptoms occurred within a timeframe which, given the medical understanding of the disorder’s etiology, it is medically acceptable to infer causation.” *de Bazan v. Sec’y of Health & Hum. Servs.*, 539 F.3d 1347, 1352 (Fed. Cir. 2008). The explanation for what is a medically acceptable timeframe must align with the theory of how the relevant vaccine can cause an injury (*Althen* prong one’s requirement). *Id.* at 1352; *Shapiro v. Sec’y of Health & Hum. Servs.*, 101 Fed. Cl. 532, 542 (2011), *recons. denied after remand*, 105 Fed. Cl. 353 (2012), *aff’d mem.*, 503 F. Appx. 952 (Fed. Cir. 2013); *Koehn v. Sec’y of Health & Hum. Servs.*, No. 11-355V, 2013 WL 3214877 (Fed. Cl. Spec. Mstr. May 30, 2013), *mot. for review denied*, (Fed. Cl. Dec. 3, 2013), *aff’d*, 773 F.3d 1239 (Fed. Cir. 2014).

B. *Law Governing Analysis of Fact Evidence*

The process for making determinations in Vaccine Program cases regarding factual issues begins with consideration of the medical records. Section 11(c)(2). The special master is required to consider “all [] relevant medical and scientific evidence contained in the record,” including “any diagnosis, conclusion, medical judgment, or autopsy or coroner's report which is contained in the record regarding the nature, causation, and aggravation of the petitioner's illness, disability, injury, condition, or death,” as well as the “results of any diagnostic or evaluative test which are contained in the record and the summaries and conclusions.” Section 13(b)(1)(A). The special master is then

required to weigh the evidence presented, including contemporaneous medical records and testimony. *See Burns v. Sec'y of Health & Hum. Servs.*, 3 F.3d 415, 417 (Fed. Cir. 1993) (determining that it is within the special master's discretion to determine whether to afford greater weight to contemporaneous medical records than to other evidence, such as oral testimony surrounding the events in question that was given at a later date, provided that such determination is evidenced by a rational determination).

As noted by the Federal Circuit, “[m]edical records, in general, warrant consideration as trustworthy evidence.” *Cucuras*, 993 F.2d at 1528; *Doe/70 v. Sec'y of Health & Hum. Servs.*, 95 Fed. Cl. 598, 608 (2010) (“[g]iven the inconsistencies between petitioner's testimony and his contemporaneous medical records, the special master's decision to rely on petitioner's medical records was rational and consistent with applicable law”), *aff'd*, *Rickett v. Sec'y of Health & Hum. Servs.*, 468 F. App'x 952 (Fed. Cir. 2011) (non-precedential opinion). A series of linked propositions explains why such records deserve some weight: (i) sick people visit medical professionals; (ii) sick people attempt to honestly report their health problems to those professionals; and (iii) medical professionals record what they are told or observe when examining their patients in as accurate a manner as possible, so that they are aware of enough relevant facts to make appropriate treatment decisions. *Sanchez v. Sec'y of Health & Hum. Servs.*, No. 11–685V, 2013 WL 1880825, at *2 (Fed. Cl. Spec. Mstr. Apr. 10, 2013); *Cucuras v. Sec'y of Health & Hum. Servs.*, 26 Cl. Ct. 537, 543 (1992), *aff'd*, 993 F.2d 1525 (Fed. Cir. 1993) (“[i]t strains reason to conclude that petitioners would fail to accurately report the onset of their daughter's symptoms”).

Accordingly, if the medical records are clear, consistent, and complete, then they should be afforded substantial weight. *Lowrie v. Sec'y of Health & Hum. Servs.*, No. 03–1585V, 2005 WL 6117475, at *20 (Fed. Cl. Spec. Mstr. Dec. 12, 2005). Indeed, contemporaneous medical records are often found to be deserving of greater evidentiary weight than oral testimony—especially where such testimony conflicts with the record evidence. *Cucuras*, 993 F.2d at 1528; *see also 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), *cert. denied*, *Murphy v. Sullivan*, 506 U.S. 974 (1992) (citing *United States v. United States Gypsum Co.*, 333 U.S. 364, 396 (1947) (“[i]t has generally been held that oral testimony which is in conflict with contemporaneous documents is entitled to little evidentiary weight.”)).

However, the Federal Circuit has also noted that there is no formal “presumption” that records are accurate or superior on their face to other forms of evidence. *Kirby v. Sec'y of Health & Hum. Servs.*, 997 F.3d 1378, 1383 (Fed. Cir. 2021). There are certainly situations in which compelling oral 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) (“like 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*, 2005 WL 6117475, at *19 (“[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*, 569 F.3d at 1379; *Bradley v. Sec’y of Health & Hum. Servs.*, 991 F.2d 1570, 1575 (Fed. Cir. 1993).

When witness testimony is offered to overcome the presumption of accuracy afforded to contemporaneous medical records, such testimony must be “consistent, clear, cogent, and compelling.” *Sanchez*, 2013 WL 1880825, at *3 (citing *Blutstein v. Sec’y of Health & Hum. Servs.*, No. 90–2808V, 1998 WL 408611, at *5 (Fed. Cl. Spec. Mstr. June 30, 1998)). In determining the accuracy and completeness of medical records, the Court of Federal Claims has listed four possible explanations for inconsistencies between contemporaneously created medical records and later testimony: (1) a person's failure to recount to the medical professional everything that happened during the relevant time period; (2) the medical professional's failure to document everything reported to her or him; (3) a person's faulty recollection of the events when presenting testimony; or (4) a person's purposeful recounting of symptoms that did not exist. *La Londe v. Sec’y of Health & Hum. Servs.*, 110 Fed. Cl. 184, 203–04 (2013), *aff’d*, 746 F.3d 1334 (Fed. Cir. 2014). In making a determination regarding whether to afford greater weight to contemporaneous medical records or other evidence, such as testimony at hearing, there must be evidence that this decision was the result of a rational determination. *Burns*, 3 F.3d at 417.

C. *Standards for Ruling on the Record*

I am resolving this claim on the filed record. The Vaccine Act and Rules not only contemplate but encourage special masters to decide petitions on the papers where (in the exercise of their discretion) they conclude that doing so will properly and fairly resolve the case. Section 12(d)(2)(D); Vaccine Rule 8(d). The decision to rule on the record in lieu of hearing has been affirmed on appeal. *Kreizenbeck v. Sec’y of Health & Hum. Servs.*, 945 F.3d 1362, 1366 (Fed. Cir. 2020); *see also Hooker v. Sec’y of Health & Hum. Servs.*, No. 02-472V, 2016 WL 3456435, at *21 n.19 (Fed. Cl. Spec. Mstr. May 19, 2016) (citing numerous cases where special masters decided case on the papers in lieu of hearing and that decision was upheld). I am simply not required to hold a hearing in every matter, no matter the preferences of the parties. *Hovey v. Sec’y of Health & Hum. Servs.*, 38 Fed. Cl. 397, 402–03 (1997) (determining that special master acted within his discretion in denying evidentiary hearing); *Burns*, 3 F.3d at 417; *Murphy v. Sec’y of Health & Hum. Servs.*, No. 90-882V, 1991 WL 71500, at *2 (Fed. Cl. Spec. Mstr. Apr. 19, 1991).

ANALYSIS

As in many Program cases, determination of the relevant injury is critical to this claim’s success. *Broekelschen*, 618 F.3d at 1346. Although this is not because *Petitioner’s diagnosis*

herein is in dispute. On the contrary, it is *not* disputed that Petitioner was properly diagnosed with MS.

Rather, the question presented is whether the claim can be narrowed only to focusing on TM as the alleged injury. It is in this regard that diagnosis is important, because the Program has treated TM very differently from MS. Moreover, Petitioner expressly is *not* attempting to prove her MS was vaccine-caused. Opp. at 15. Rather, she argues the flu vaccine caused her to incur TM—and at most allows that her experiencing TM *increased* her risk of MS, although she does not purport to explain how her subsequent MS diagnosis relates otherwise.

TM presents usually as a one-time, monophasic (hence non-recurring) CNS injury—although it can leave lasting deficiencies in a patient who has experienced it.¹⁰ MS, by contrast, is typically chronic, featuring relapses or even worsening progression. *Porch v. Sec’y of Health & Hum. Servs.*, No. 17-802V, 2023 WL 21875, at *21 (Fed. Cl. Spec. Mstr. Jan. 3, 2023); *Samuels v. Sec’y of Health & Hum. Servs.*, No. 17-071V, 2020 WL 2954953, at *18-19 (Fed. Cl. May 1, 2020). MS can also be subclinical for long periods of time, with its characteristic lesions seen often only *after* clinical manifestations. *Samuels*, 2020 WL 2954953, at *18. And it is not well-understood what causes MS in the first place—with far more evidence linking vaccines to acute, self-limiting illnesses (like TM) than to MS. *Id.* at 21. Thus, even if both *involve* nerve demyelination, MS and TM are not congruent illnesses. Indeed, MS is a far more ominous diagnosis, since its course can prove significantly debilitating over time, whereas TM resolves faster.

TM has often been deemed a compensable vaccine injury, as evidenced by numerous prior Program decisions. *See, e.g., Raymo v. Sec’y of Health & Human Servs.*, No. 11-654V, 2014 WL 1092274, at *23 (Fed. Cl. Spec. Mstr. Feb. 24, 2014) (finding causal relationship between flu vaccine and TM). But I have observed a distinction between acute demyelinating injuries that cause sudden and abrupt injury to the central nervous system, like TM or acute disseminated encephalomyelitis (“ADEM”), and those that are chronic, relapsing/remitting, and/or progressive, like MS. *See e.g., Morgan v. Sec’y of Health & Hum. Servs.*, No. 15-1137V, 2019 WL 7498665, at *16 (Fed. Cl. Spec. Mstr. Dec. 4, 2019), *mot. for review den’d*, 148 Fed. Cl. 454 (2020), *aff’d*, 850 F. App’x 775 (Fed. Cir. 2021); *Samuels v. Sec’y of Health & Hum. Servs.*, No. 17-071V, 2020 WL 2954953, at *18 (Fed. Cl. Spec. Mstr. May 1, 2020) (MS with first presenting symptom ADEM).¹¹

¹⁰ See S. PLOTKIN ET AL., PLOTKIN’S VACCINES t874 (7th ed. 2018) (listing flaccid diplegia and atrophy as sequelae between 3 months and one year after occurrence).

¹¹ The Vaccine Program recognizes the distinction between monophasic, self-limiting diseases and those that are chronic/relapsing in other injury contexts as well. For example, while Guillain-Barré syndrome (an acute peripheral nervous system demyelinating disease) after receipt of the flu vaccine is a Table claim, chronic inflammatory demyelinating polyneuropathy, or “CIDP,” (what is often mischaracterized as “chronic GBS”) is not. *Nieves v. Sec’y of Health & Hum. Servs.*, No. 18-1602V, 2023 WL 3580148, at *n43 (Fed. Cl. Spec. Mstr. May 22, 2023), *mot. for*

Thus, the flu vaccine has not consistently (or credibly) been linked to chronic and relapsing-remitting CNS illnesses. *Doles v. Sec'y of Health & Hum. Servs.*, 167 Fed. Cl. 525, 533 (2023) (ruling that study showing a link between vaccines and acute, non-MS demyelinating conditions could not be inferred to support a theory linking vaccines and MS), *appeal docketed*, No. 17-642 (Fed. Cir. Sep. 25, 2023); *Wei-Ti Chen v. Sec'y of Health & Human Servs.*, No. 16-634V, 2019 WL 2121208, at *22 (Fed. Cl. Spec. Mstr. Apr. 19, 2019) (insufficient evidence was provided to support a causal connection between the flu vaccine and petitioner's subsequent development of neuromyelitis optica spectrum disorder, which is chronic and relapsing/remitting like MS); *Hunt v. Sec'y of Health & Human Servs.*, No. 12-232V, 2015 WL 1263356, at *15 (Fed. Cl. Spec. Mstr. Feb. 23, 2015) (denying entitlement where MS was the alleged injury, but the causation evidence related to ADEM) *mot. for review den'd*, 123 Fed.Cl. 509 (2015). Existing medical and scientific literature simply, and more compellingly, is supportive of the finding that a vaccine could cause a one-time injury (even if it results in secondary, lingering sequelae)—not a chronic and persistent condition that unpredictably waxes and wanes, long after the vaccine's initial impact has occurred.

Equally important is the fact that TM can often constitute the *initial presenting symptom* of MS, with subsequent flares occurring later in time. This is consistent with one commonly-accepted diagnostic criteria for MS—that it requires proof of *two* manifestations (e.g., lesions or symptoms) separated by time and “space” (meaning a second manifestation/flare impacting the body elsewhere). *Hunt*, 2015 WL 1263356, at *11 (noting that an MS diagnosis traditionally requires “at least two events disseminated in time and space” (internal quotation marks omitted)). Thus, when what initially appears to be TM is followed by subsequent neurologic symptoms or other corroborating proof of a more chronic condition, the claimant's actual injury is *not limited to* the initially-diagnosed TM—and TM is no longer a diagnostically-correct classification for the injured party's presentation. *Pek v. Sec'y of Health & Hum. Servs.*, No. 16-0736V, 2020 WL 1062959, at *16 (Fed. Cl. Spec. Mstr. Jan. 31, 2020) (“I note that in prior cases I have generally observed a distinction between acute demyelinating injuries that cause sudden and abrupt injury to the CNS (e.g., TM), and those that are chronic, relapsing/remitting, and/or progressive, like MS”). Even if the individual's first symptoms manifestations fit the diagnostic criteria for TM but not MS (as Petitioner observes in her briefing), a petitioner's *later* health history may provide medical details missing at the start, subsequently illuminating the true, chronic nature of the injury.

review den'd, 167 Fed. Cl. 422 (2023) In fact, I have noted in prior cases that the evidence associating CIDP with the flu vaccine is significantly less robust than what links the vaccine to GBS. *Mason v. Sec'y of Health & Hum. Servs.*, No. 17-1383V, 2022 WL 600415, at *22 (Fed. Cl. Spec. Mstr. Feb. 4, 2022) (contrasting the strength of evidence supporting a link between the flu vaccine and CIDP versus that supporting a link to GBS). At bottom, chronic versions of a disease involve different biological inputs and immunologic “errors” that impact physiologic processes differently from a one-time, transient, acute “hit” to the immune system that a vaccine might trigger. *Houston v. Sec'y of Health & Hum. Servs.*, No. 18-420V, 2021 WL 4259012, at *16 (Fed. Cl. Spec. Mstr. Aug. 19, 2021) (discussion of the differences in pathogenesis between GBS and CIDP).

The individual, in retrospect, did *not* suffer from TM, despite evidence supporting the diagnosis at first glance.

Given the above, I have never found entitlement in a case where a Petitioner’s initial presenting illness may have *appeared* to be an acute event (like TM or ADEM), but later turned out to be the first manifestation of MS.¹² Such claimants have simply been unable to establish preponderantly that (a) the MS could have been caused by vaccination in the first place, or (b) the vaccine likely caused the acutely-presenting first symptom, but then that initial adverse event was *also* the “but for” cause of the petitioner’s subsequently-diagnosed chronic condition (as opposed to a first manifestation of the subsequent illness). *See Pek*, 2020 WL 1062959, at *16; *Maciel v. Sec’y of Health & Hum. Servs.*, No. 15-362V, 2018 WL 6259230, at *23 (Fed. Cl. Spec. Mstr. Oct. 12, 2018), *mot. for review denied* (Fed. Cl. Apr. 1, 2019); *L.Z. v. Sec’y of Health & Hum. Servs.*, No. 14-920V, 2018 WL 5784525, at *18 (Fed. Cl. Spec. Mstr. Aug. 24, 2018).

Here, the record preponderantly establishes a number of facts undermining causality. Most significantly, the record establishes that *Petitioner experienced MS*—not a single, self-limiting occurrence of TM. Ex. 8 at 39–40 (official diagnosis of MS and beginning of MS-specific treatment plan). No treaters proposed that TM characterizes Petitioner’s overall course, even if they reasonably believed at the outset of her presentation that Petitioner had TM. Rather, and after time progressed and Petitioner’s course lengthened, it was concluded that what appeared to be TM was a first/initial MS flare, with Petitioner ultimately receiving an MS diagnosis that has preponderant record support. *Id.* Based on such a record, I cannot find (drawing upon my experience as a special master in deciding prior, comparable cases) that the flu vaccine could have caused it—or was responsible for an isolated “case” of TM that preceded it but morphed into MS for unrelated reasons. Petitioner’s TM was the presenting component of a greater condition—so

¹² Admittedly, a few special masters have gone in the opposite direction, and granted compensation in MS cases—finding either direct causality or aggravation of preexisting, if subclinical, MS. *See, e.g., Gardner v. Sec’y of Health & Hum. Servs.*, No. 17-1851V, 2023 WL 9288070 (Fed. Cl. Spec. Mstr. Dec. 21, 2023); *Robinson v. Sec’y of Health & Hum. Servs.*, No. 14-952V, 2021 WL 2371721, at *25 (Fed. Cl. Spec. Mstr. Apr. 12, 2021); *Hitt v. Sec’y of Health & Human Servs.*, No. 15-1283V, 2020 WL 831822, at *9–10 (Fed. Cl. Spec. Mstr. Jan. 24, 2020).

However, the significant aggravation cases are distinguishable factually, since it has usually been conceded or found therein that the individual in question likely had at least “subclinical” MS before vaccination—something not contended in this case. And in any event (and disregarding the fact that I am not bound by the decisions of other special masters), I do not (based on my own experiencing deciding such claims) concur that the transient impact of a single vaccine could likely worsen MS—since MS flares are known to be triggered by a *large number* of transient occurrences (heat, stress, an infection, etc.), but those triggers are not deemed directly responsible for the entirety of a claimant’s subsequent disease (which will inherently feature remitting/relapsing occurrences of symptoms).

Otherwise, my review of those contrary decisions does not reveal any reasoned efforts to grapple with the distinctions between acute and chronic injuries, or the acknowledged fact that what initially may seem to be a one-time event proves otherwise. Rather, the assumption in these decisions appears to have been that if a vaccine can cause *one kind* of CNS autoimmune demyelinating injury, it can cause another.

because she does not seek to prove her MS was vaccine-caused (except as a secondary matter at most),¹³ she cannot prevail.

Because I am opting to dismiss the claim even before Petitioner has had the chance to offer expert support for her claim, I will explain why such input would not alter the outcome. As noted, I am drawing upon my expertise ruling on comparable claims in which a single, one-time demyelinating event did not capture the claimant’s actual illness—even if at first glance it appeared otherwise. In such similar petitions, I have heard live testimony on the question and/or reviewed lengthy expert reports. I therefore have sufficient familiarity with the subject to expect that any evidence submitted herein would likely repeat prior arguments I have considered but rejected.

Moreover, special masters are empowered to determine how best to resolve a claim, and in what manner—including whether to allow discovery at all. Section 12(d)(3)(B)(“[t]here may be no discovery in a proceeding on a petition other than the discovery required by the special master”); *Kreizenbeck*, 945 F.3d at 1363. Matters do not run on automatic pilot, with claimants setting the terms for what discovery and evidence will be permitted, and/or how long the process to generate those materials will take. In addition, experts are not *de rigueur* in every single Vaccine Act case. And here, a medical expert could not gainsay the medical/scientific fact that TM and MS are *distinguishable*—and that TM can constitute an initial MS presenting symptoms, in the unfortunate case that an individual’s neurologic symptoms subsequently progress or deteriorate.

As a result, in this matter I am confronted with a causation theory that I have evaluated repeatedly before, in matters where I was required to exhaustively review medical and scientific evidence on questions of causation. There is no call for repeating this exercise solely because the claimant is different. I am also unlikely to revisit my prior determinations on the subject absent some critical or new item of evidence that justifies reconsideration—and Petitioner has pointed to no new science or medical discoveries that would support the conclusion that an initial, vaccine-caused MS flare, first manifesting as TM, *in turn* is likely casual of MS writ large.¹⁴

The overall record herein strongly supports an MS diagnosis, for the reasons set forth above—and contemporaneous treaters in fact revised their diagnostic views accordingly, as time

¹³ I would, however, still dismiss the claim even if Petitioner had advanced the alternative theory that her MS was vaccine-caused, relying on the reasoning from prior cases. *See, e.g., Pek*, 2020 WL 1062959.

¹⁴ While claimants often protest that finding this kind of evidence is difficult (and thus that to “require” it is to demand certainty of proof, despite the Program’s preponderance standard), I note that in many other recent cases, claimants have cited some new scientific studies about an observed link between the Epstein-Barr virus (“EBV”) and MS. *See, e.g., Nieves*, 2023 WL 3580148, at *20. But these new studies are usually offered to bulwark causation theories involving molecular mimicry. They do not tend to make it more likely than not that the flu virus—let alone the vaccine intended to ward against it—would also likely cause MS. Indeed—there are, to my knowledge, *no comparable studies whatsoever* linking the flu virus to MS in the same manner (nor is there even an EBV vaccine). Thus, the EBV-oriented evidence only underscores the absence of comparable evidence that could be referenced in this case.

progressed and testing and other clinical evidence came in. As a result, the fact that the flu vaccine “can cause” TM does not assist Petitioner—for TM does not accurately describe her overall injury, or even an injury apart from her later-diagnosed MS.¹⁵ It is for these reasons that dismissal is warranted.

CONCLUSION

Petitioner’s injury herein is not limited to TM. Rather, her initial TM was itself a first MS flare—and I have repeatedly found that MS is not likely vaccine-caused. Accordingly, she cannot establish entitlement to an award of damages, and I must **DISMISS** the claim.¹⁶

IT IS SO ORDERED.

s/Brian H. Corcoran
Brian H. Corcoran
Chief Special Master

¹⁵ While it is conceivable that an individual could experience TM due to vaccination, and then *years later* suffer MS independently, the record herein is not consistent with such an occurrence. Instead, it suggests the disease process that seemed to cause TM was rapidly progressing in real time, with treaters coming to the determination that MS was the injury less than four months after the TM diagnosis.

¹⁶ Pursuant to Vaccine Rule 11(a), the parties may expedite entry of judgment by filing a joint notice renouncing their right to seek review.