UNITED STATES DISTRICT COURT
FOR THE EASTERN DISTRICT OF PENNSYLVANIA

IN RE: NATIONAL FOOTBALL LEAGUE PLAYERS' CONCUSSION INJURY LITIGATION	:	No. 2:12-md-02323-AB
	:	MDL No. 2323
	:	**Hon. Anita B. Brody**
THIS DOCUMENT RELATES TO: APPEAL OF SETTLEMENT CLASS MEMBER [redacted] REGARDING DENIAL OF MONETARY AWARD	:	

INTRODUCTION

On March 13, 2019, [redacted], a Retired NFL Player and Class Member under the Amended Class Action Settlement, filed a claim for benefits under the Agreement. He received a Qualifying Diagnosis of Level 2 Neurocognitive Impairment outside of the Baseline Assessment Program from a Qualified MAF Physician. It was his burden to submit "evaluation and evidence generally consistent with the diagnostic criteria" specified in the Settlement.[1]

The Claims Administrator reviewed the diagnosis and concluded that Mr. [redacted] failed to meet his burden. Mr. [redacted] subsequently filed an appeal. Because he has not established by clear and convincing evidence that the Claims Administrator's decision was wrong,[2] the Appeal is denied.

[1] *See* Settlement Agreement, Exhibit 1(2)(b). The parties to the Settlement Agreement have defined "generally consistent" to mean that the evidence "has more elements or characteristics in common" with the diagnostic criteria than "elements or characteristics that differ" from the criteria. *See* Settlement Portal, *Frequently Asked Questions*, FAQ #101.

[2] *See* Settlement Agreement, Section 9.8. The Special Masters must decide an appeal of a Monetary Award based on a showing by the appellant of clear and convincing evidence that the determination of the Claims Administrator was incorrect. *See* Order Appointing Special Masters, at 5. "Clear and convincing evidence" is a recognized intermediate standard of proof—more demanding than preponderance of the evidence, but less demanding than proof beyond a reasonable doubt. *In re Fosamax Alendronate Sodium Prods. Liab. Litig.*, 852 F.3d 268, 285-86 (3d Cir. 2017) ("Black's Law Dictionary defines clear and convincing evidence as 'evidence indicating that the thing to be proved is highly probable or reasonably certain.'").

FACTUAL AND PROCEDURAL BACKGROUND

This Appeal concerns the Qualifying Diagnosis that Mr. [redacted] received on January 28, 2019 from Dr. [redacted], a Qualified MAF Physician and board-certified neurologist. Doc. 205285. This is the second claim that Mr. [redacted] has filed under the Settlement Agreement. Since Mr. [redacted] filed his first claim in April 2017, he has received Certification of a Qualifying Diagnosis from three different physicians, and his claim for benefits has been denied four times. Doc. 219600; Doc. 190956; Doc. 181360; Doc. 173499.

Mr. [redacted] first received a Pre-Effective Date diagnosis of Alzheimer's Disease by Dr. [redacted], a neurosurgeon who was neither a Qualified BAP Provider nor a Qualified MAF Physician and had never previously treated Mr. [redacted] Doc. 63092. Dr. [redacted] based his diagnosis on review of Mr. [redacted] previous medical records from other providers. Doc. 128548, at 2. The Claims Administrator requested additional documentation because Mr. [redacted] medical records were not from the same physician who provided the Qualifying Diagnosis. Doc. 78442.

Dr. [redacted], a board-certified neurologist who was neither a Qualified BAP Provider nor a Qualified MAF Physician, but had treated Mr. [redacted] for multiple years, then provided a second Qualifying Diagnosis in September 2017. Doc. 128548. Drawing support from two neuropsychological evaluations (from 2013 and 2015) performed by Dr. [redacted], Dr. [redacted] diagnosed Mr. [redacted] with Level 2 Neurocognitive Impairment, which she back-dated to April 4, 2013. She concluded that additional testing was medically unnecessary. *Id*. at 6.

Because Mr. [redacted] date of diagnosis preceded the Settlement Effective Date, the Appeals Advisory Panel automatically reviewed the claim. An AAP Reviewer found that the evidence of functional impairment presented by Dr. [redacted] was not generally consistent with a Clinical Dementia Rating score of 2.0. Doc. 173340. An AAP Consultant subsequently determined that both of the neuropsychological evaluations performed by Dr. [redacted] were inconsistent with the Settlement criteria because of significant differences in the test battery, inadequate assessment of validity, incompleteness of reporting, and "variability and inconsistency in scores between the 2013 and 2015 evaluations." Doc. 172807. On May 29, 2018, following this review by the AAP, the Claims Administrator denied Mr. [redacted] claim. Doc. 173499.

Mr. [redacted] timely appealed. Doc. 178002. In support of that appeal, he provided additional evidence including an email sent by [redacted] to Dr. [redacted] in 2016 discussing Mr. [redacted] functional status, and documentation of a primary care appointment in 2017 with Dr. [redacted]. Doc. 177679; Doc. 177680. Special Master Pritchett remanded the claim to the Claims Administrator for re-review of the issues raised. The AAP found that the supplemental records failed to provide support for the claim, and again concluded that "[t]he poor validity on neuropsychological testing continues to preclude establishment of Level 2.0 Neurocognitive Impairment as a diagnosis." Doc. 180054. The Claims Administrator denied Mr. [redacted] appeal on August 2, 2018. Doc. 181360.

For a second time, Mr. [redacted] timely appealed, disputing the factual and legal conclusions of the AAP. Doc. 184308. The AAP reconsidered the claim, and again explained that

the available evidence—including medical reports and neuropsychological examinations—was "not generally consistent with the Settlement Criteria for Level 2.0 Neurocognitive Impairment." Doc. 189757. Special Master Pritchett, adopting the analysis from the AAP, denied Mr. [redacted] appeal on November 19, 2018. Doc. 190956.

In January 2019, MAF Physician Dr. [redacted] diagnosed Mr. [redacted] with Level 2 Neurocognitive Impairment. Based on that diagnosis, Mr. [redacted] filed a new claim (this one, his second) on March 13, 2019. Doc. 203180. In his diagnosis, Dr. [redacted] certified that neuropsychological testing was unnecessary. Doc. 203181 at 4. The Claims Administrator subsequently provided notice of multiple deficiencies in the medical documentation from Dr. [redacted] most of which related to the absence of those test results. Doc. 203406. The Claims Administrator further engaged in a dialogue with Dr. [redacted] with specific questions addressing the evidentiary issues. Doc. 216517.

On January 16, 2020, the Claims Administrator denied Mr. [redacted] claim, finding that the Qualifying Diagnosis was not generally consistent with the diagnostic criteria in the Settlement Agreement. Doc. 219600. Mr. [redacted] again, timely appealed. Doc. 220914.

DISCUSSION

There are four diagnostic criteria that must be satisfied for a Qualifying Diagnosis of Level 2 Cognitive impairment.[3] The two at issue here are criterion (ii) ("evidence of a severe cognitive decline . . . as determined by and in accordance with [] standardized neuropsychological testing") and criterion (iii) ("functional impairment generally consistent with the criteria set forth in . . . Clinical Dementia Rating (CDR) scale Category 2.0 (Moderate) in the areas of Community Affairs, Home & Hobbies, and Personal Care.").

Dr. [redacted] did not facilitate the administration of neuropsychological testing as required by criterion (ii). This would render Mr. [redacted] Qualifying Diagnosis inconsistent with the criteria unless, as the Settlement provides, "the diagnosing physician can certify . . . that certain testing in 2(a)(i)-(iv) is medically unnecessary because the Retired NFL Football Player's dementia is so severe."[4]

On the MAF Diagnosing Physician Certification Form, Dr. [redacted] checked the box indicating that neuropsychological testing was medically unnecessary. Doc. 203181 at 4. In support of this determination, Dr. [redacted] stated the following: "clinical dementia rating [CDR] scale score: 2." *Id.* The corresponding medical records from January 2019 provide no further justification; in fact, there is no indication that Dr. [redacted] even considered the possibility of neurocognitive testing during his assessment of Mr. [redacted].[5] Doc. 203184.

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[3] *Id.* Exhibit 1(2)(a)(ii)-(iii).

[4] *Id.* Exhibit 1(2)(b).

[5] In email correspondence with the Claims Administrator, Dr. [redacted] stated: "It was my understanding that in order for a former NFL player to qualify for a diagnosis of level 1 or 2 neurocognitive impairment, he had to have a diagnosis of Alzheimer's disease or a Clinical Dementia Rating (CDR) score of 1 or 2 or fulfill the criteria in neuropsychological testing." Doc. 220915 at 4.

On January 16, 2020, the Claims Administrator denied Mr. [redacted] claim largely because Dr. [redacted] failed to adequately justify why neuropsychological testing was medically unnecessary. Doc. 219600. The Claims Administrator also found that Dr. [redacted] assessment of Mr. [redacted] functional ability was not generally consistent with the Settlement criteria for Level 2 Neurocognitive Impairment. *Id*. This denial followed several attempts by the Claims Administrator to contact Dr. [redacted] and obtain a more thorough explanation that might address the issues raised in the Notice of Preliminary Review from March 2019. Doc. 203406. In response to an email from the Claims Administrator, Dr. [redacted] provided the following further explanation of his judgment:

> We calculated a CDR score of 2 because the preponderance of [Mr. [redacted] day to day function measurements for memory, orientation, judgment and problem solving, community affairs, home and hobbies, and personal functions resulted in a score of 2. A CDR score of 2 is unequivocal evidence of a moderate degree of dementia. Neuropsychological testing would be difficult to perform in patients with moderate dementia. It takes 4-5 hours to perform. It take [sic] a concerted effort and a great deal of motivation and concentration to complete this test. Mr. [redacted] would be incapable of completing such an evaluation.

Doc. 216517 at 4. Does this explanation satisfy the certification requirement of Exhibit 1(2)(b)? Late last month, following the Parties' joint advice, I adopted a "reasonably determined" test to evaluate the Claims Administrator's review of a clinician's certification of the futility of testing: [6]

> "Reasonably determined" means that the clinician's choices are cognizable as an application of the Settlement's narrow ("unless") exception to the testing requirement, *i.e.,* that the impairment was "so severe" that testing is "medically unnecessary." Another way to put this is that it was reasonable to have concluded that the testing would not generate valid results.
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> Under the Settlement, particularly Section 8.6(b), the Claims Administrator has the authority to verify the sufficiency of both prongs of that reasonableness inquiry: How *severe* was the impairment; and, Why does the impairment's severity make the testing *unnecessary*? That is not the same as saying that the Claims Administrator's supervisory authority is plenary. The Parties have interpreted the agreement to mean that the Claims Administrator cannot disagree with the clinician's Certification merely because it would have made a different choice. The clinician's articulated reasons for certifying must be *unreasonable*. But the Claims Administrator possesses ample authority to require a complete explanation, and to ensure it is internally consistent.

That case, like this one, also considered the relationship between the CDR score and the certification requirement:[7]

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[6] *See* Special Master Opinion on Certification, May 27, 2020, available at https://www nflconcussionsettlement.com/Docs/physician_certification_testing_sm.pdf.
[7] *Id*.

> [A] Qualifying Diagnosis of Level 2 Impairment generally requires functional impairment consistent with a CDR of 2.0 *as well as* evidence of cognitive decline, established through testing (Settlement Agreement, Exhibit 1. at § 2(a)(ii)), "unless the diagnosing physician can certify" that the neuropsychological testing "is medically unnecessary because the Retired NFL Football Player's dementia is so severe." *Id*. at 3, § 2(b). Because most diagnoses require both functional loss *and* testing/certification, a given functional score can't necessarily determine severity or medical necessity for the purposes of certification. The inquiries should be distinct.
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> The appropriate focus—what the Certification must reasonably determine—is whether the cognitive impairment was so severe as to make testing medically unnecessary. Functional impairment at the 2.0 level—designated as 'moderate' in the CDR scoring sheet—may be probative of that standard's satisfaction. But there are links in the chain of argument from functional impairment to Certification that the Claims Administrator may seek to be made explicit. A CDR score of 2.0, standing alone, is neither preclusive, necessary nor sufficient. It is a piece of the puzzle.

This recent opinion provides a template for my analysis of Mr. [redacted] appeal.

In the Denial Notice, the Claims Administrator noted that a CDR score of 2.0 alone does not necessarily provide adequate support for granting an exception to the neuropsychological testing requirement "because the Settlement Agreement specifically references a CDR score of 2.0 in the diagnostic criteria for the Qualifying Diagnosis of Level 2 Neurocognitive Impairment." Doc. 219600. In response, counsel for Mr. [redacted] argues that the Claims Administrator has exceeded its authority by drawing "a legal conclusion defining the standards for concluding when medical testing is unnecessary." Doc. 220914. But, as I have previously determined, distinguishing between a CDR Score and the rationale for a certification is reasonable.

It was consequently within the authority of the Claims Administrator to require a more complete explanation from Dr. [redacted]—one which described more fully the link between the asserted CDR score and the conclusion that testing was unnecessary. That explanation here came in two parts, which the Claims Administrator properly probed for their coherence.

First, Dr. [redacted] stated that "[n]europsychological testing would be difficult to perform" for someone with a CDR score of 2.0. Doc. 216517. Stating that a task will be *difficult* for a person does not compel the conclusion that testing would not generate valid results. Moreover, Dr. [redacted] did not describe why testing Mr. [redacted] would be more difficult than for other individuals exhibiting symptoms consistent with a CDR score of 2.0. That Dr. [redacted] *might* have offered such a justification—as Mr. [redacted] asserts in his brief, citing to other portions of the record—is not enough to make the explanation that Dr. [redacted] *actually* provided complete.

The gravamen of Dr. [redacted] explanation, however, followed the remarks about difficulty: "It [testing] takes 4-5 hours to perform. It take [sic] a concerted effort and a great deal of motivation and concentration to complete this test. Mr. [redacted] would be incapable of completing such an evaluation." Doc. 216517 at 4. The best reading of these phrases is that Dr. [redacted] was drawing an inference—based on his clinical experience with Mr. [redacted]—that his patient lacked the

wherewithal to complete testing, quite apart from his CDR score. That impression is not, however, well founded. For one, it is undermined by Dr. [redacted] (erroneous) articulation of the Settlement's bases for a Diagnosis, offered in the same correspondence, which he described as requiring either testing *or* a CDR score of 1 *or* 2. *Id*. That suggests that he improperly discounted the importance of neuropsychological testing as a basis for a valid claim. Moreover, as the Notice of Denial explained, the rest of the medical record is simply not consistent with Dr. [redacted] conclusion:

> The description of the Player in the note includes documentation of an MMSE score of 20/30, being oriented to month, day, year, state, and doctor's office, and functional abilities like being able to perform one serial-7 calculation, being able to register three words and recall one of them after two minutes, and being able to name, repeat, and follow a three-step command, read a sentence and follow instructions, write a sentence, and copy a figure.

Doc. 219600 (internal citation omitted). In response, Mr. [redacted] counsel argues that past medical records "fully support Dr. [redacted] findings," specifically stating that the 2013 and 2015 examinations performed by Dr. [redacted] were found to be "invalid due to inadequate effort levels" and that "[redacted] has already proven he cannot complete a neurological exam because his cognitive condition has robbed him of the effort, concentration, and patience necessary to do so." Doc. 220914 at 4. But Mr. [redacted] did, in fact, successfully complete testing in 2013 and 2015 with Dr. [redacted] Doc. 63073 at 98-104, 132-140. The previous appeals—decided on factual grounds not subject to relitigating now—concluded that the results were not consistent with the Settlement criteria due to serious flaws in testing. Doc. 190956; Doc. 189757; Doc. 220914 at 4. The key inconsistencies, noted by the AAP and adopted by Special Master Pritchett, included "problems with validity, using test batteries that were significantly different from the Settlement battery, and showing variability and inconsistency between the examinations." Doc. 189757; Doc. 172807.

As I concluded in the recently-released Special Master Opinion on Certification, "if a clinician offers a coherent and reasonably complete explanation of why that standard is satisfied, the Claims Administrator should accept that Certification even if it would have made a different choice." Here, the Claims Administrator's problems with Dr. [redacted] explanation went beyond disagreement. It reasonably found that his certification was insufficiently justified.

Second, the Claims Administrator concluded that the evidence presented was not generally consistent with criterion (iii) as Mr. [redacted] received CDR scores of 1.0 (mild impairment) in two of the three "functional impairment" categories.[8] Doc. 219600. The Claims Administrator reached out to Dr. [redacted] and requested an explanation as to how Mr. [redacted] scores in the relevant categories—Community Affairs, Personal Care, and Home & Hobbies—were generally consistent with criteria for Level 2 Neurocognitive Impairment. Doc. 216517. Dr. [redacted] wrote:

[8] Mr. [redacted] displayed scores of 1.0 in Community Affairs and Personal Care. Doc. 205286 at 10. In Home & Hobbies, both 2.0 and 3.0 are circled—but no explanation is provided as to which score is correct. *Id*. I assume that the clinician selected the 3.0 score in accordance with Settlement FAQ #111 ("In cases where . . . the diagnosing physician thinks the Player could be rated in either one of two adjacent scores, such as 1 (Mild) or 2 (Moderate), the CDR scale calls for the physician to select the score corresponding to greater impairment.")

> We arrived at the CDR score of 2 by judging that the preponderance of cognitive dysfunction was moderate in severity. Although the numeral average of his scores was 1.67, there is no score that is 1.67. It is either 0, 0.5, 1 or 2. It was my clinical judgment, that he definitely has a moderate or level 2 neurocognitive impairment and arrived at a CDR score of 2. I would be underestimating his degree of neurocognitive dysfunction if I had given him a CDR score of 1.

Doc. 216517 at 4. This averaging across categories provides no additional insight about general consistency with the diagnostic criteria for Level 2 Neurocognitive Impairment under the Settlement. It is unclear whether Dr. [redacted] is referring to the mean of all six categories or the mean of the three categories relevant to the Settlement—as both are 1.67 (assuming a score of 3.0 in Home & Hobbies). In either case, the explanation provided does not suffice. As FAQ 111 notes: "The diagnosis is not simply an average of the three scores. There is no required minimum score on any of the three areas, but the final diagnosis must be generally consistent with the scores assigned to the Player in each of the three areas." Thus, the concern about Mr. [redacted] scores in the relevant CDR categories remains unaddressed. Mr. [redacted] displayed more scores of 1.0 than scores of 2.0 or greater in the relevant CDR categories—*i.e.,* more of his scores are "unlike" the criteria than those that are "like" it. The Claims Administrator appropriately found this to be another way in which Dr. [redacted] diagnosis was not generally consistent with the Settlement criteria.

CONCLUSION

The Claims Administrator found that Dr. [redacted] had not reasonably determined that testing was medically unnecessary, and that Mr. [redacted] functional losses were not generally consistent with the Settlement Criteria. Neither decision was clearly erroneous: the Appeal is therefore denied.

Date: June 8, 2020

David Hoffman, Special Master