**UNITED STATES DISTRICT COURT**

**DISTRICT OF MASSACHUSETTS**

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| R.M.,<br><br>Plaintiff<br><br>V.<br><br>ANTHEM BLUE CROSS AND BLUE SHIELD, THE CAPITAL ONE FINANCIAL CORPORATION EMPLOYEE BENEFITS PLAN, AND CAPITAL ONE FINANCIAL CORPORATION<br><br>Defendants | CIVIL ACTION NO. |

**COMPLAINT**

**INTRODUCTION**

1. Plaintiff, R.M. brings this action against the Defendants, Anthem Blue Cross and Blue Shield ("Anthem"), The Capital One Financial Corporation Employee Welfare Benefits Plan ("the Plan"), and Capital One Financial Corporation ("Capital One") (collectively referred to as "Defendants") for violations of the Employee Retirement Income Security Act of 1974, as amended, 29 U.S.C. §§ 1001 et. seq. ("ERISA"). R.M., a minor, was a beneficiary of an ERISA welfare benefit plan administered by Anthem and insured by Capital One.
2. Plaintiff challenges Defendants': 1) unreasonable and unlawful denial of R.M.'s claim for vertebral body tethering ("VBT") surgery to treat scoliosis despite substantial medical evidence demonstrating R.M.'s entitlement to said benefits; 2) pattern of rejecting and/or

ignoring the substantial evidence supporting R.M.'s entitlement to coverage; 3) failure to provide R.M. with a full and fair review of her claim; and 4) failure to provide a reasonable claims procedure that would yield a decision on the merits of R.M.'s claim.

**JURISDICTION**

3. This Court has personal and subject matter jurisdiction over this case under 29 U.S.C. § 1132(e) and (f), without regard to jurisdictional amount or diversity of citizenship, in that the Defendants' breach of their ERISA obligations took place in this district.

**PARTIES**

4. The plaintiff, R.M., presently resides in Tyngsboro, Massachusetts. At the time the treatment began which is the subject of this Complaint, R.M. was, and continues to be, a minor dependent beneficiary of a participant in the Plan, within the meaning of 29 U.S.C. § 1002(2)(7). R.M. has standing to bring this action under 29 U.S.C. § 1132(a).
5. The Defendant, Anthem, is a for-profit corporation, with its principal place of business at 220 Virginia Avenue, Indianapolis, IN 46204. Anthem was responsible for administering claims under the Plan and making decisions regarding Plan participants' eligibility for benefits.
6. The Defendant, the Plan, is an "employee welfare benefit plan" as defined by ERISA, 29 U.S.C. §1002(1).
7. The Defendant, Capital One, is a for-profit corporation, with its principal place of business at 1680 Capital One Drive McLean, VA 22102. Capital One is responsible for insuring claims made under the Plan.

8. At all times relevant to the claims asserted in this Complaint, Anthem and Capital One purported to act as an ERISA claims fiduciaries with respect to participants of the Plan generally, and specifically with respect to R.M., within the meaning of ERISA.

**FACTS**

**The Plan.**

9. As a dependent of a Plan employee, R.M. was entitled to health insurance coverage under the Plan.

10. For R.M.'s VBT to be a covered benefit under the Plan, it must be Medically Necessary, defined in the Plan as:

> - A service or supply furnished by a particular provider is necessary if Anthem determines that it is appropriate for the diagnosis, care or treatment of the disease or injury involved.
>
> To be appropriate, the service or supply must:
> - Be care or treatment as likely to produce a significant positive outcome, and no more likely to produce a negative outcome, than any alternative service or supply, both as to the disease or injury involved and the person's overall health condition;
> - Be a diagnostic procedure, indicated by the health status of the person and be as likely to result in information that could affect the course of treatment as, and no more likely to produce a negative outcome than, any alternative service or supply, both as to the disease or injury involved and the person's overall health condition; and
> - As to diagnosis, care and treatment be no more costly (taking into account all health expenses incurred in connection with the service or supply) than any alternative service or supply to meet the above tests.

11. The Plan excludes treatment it determines to be Experimental or Investigational from coverage, defined in the Plan as the following:

> Care is considered experimental or investigational if:
>
> - There are insufficient outcomes data available from controlled clinical trials published in the peer reviewed literature to substantiate its safety and effectiveness for the illness or injury involved; or
> - It does not have a required approval for marketing by the U.S. Food

and Drug Administration; or

- A nationally-recognized medical or dental society or regulatory agency has determined, in writing, that it is experimental, investigational or for research purposes; or
- It is a type of drug, device or treatment that is the subject of a Phase 1 or Phase II clinical trial or the experimental or research arm of a Phase III clinical trial, using the definition of "phases" indicated in regulations and other official actions and publications of the FDA and Department of Health and Human Services; or
- The written protocol(s) or written informed consent used by the treating facility—or another facility studying the same drug, device, treatment or procedure—states that it is experimental, investigational or for research purposes.

12. To determine whether the requested treatment is Medically Necessary, Anthem applied its Vertebral Body Stapling and Tethering for the Treatment of Scoliosis in Children and Adolescents Coverage Guidelines, which state:

> Vertebral body stapling and vertebral body tethering as treatment of scoliosis in children and adolescents are considered investigational and not medically necessary.

**R.M.'s Claim for VBT and Anthem's Response.**

13. R.M. suffers from severe progressive scoliosis, for which "surgical intervention was clearly indicated" as described by her treating surgeon Dr. Amer Samdani.

14. R.M.'s treating providers recommended she pursue VBT as traditional surgical intervention (spinal fusion) would drastically limit her spinal motion and over time lead to worse outcomes including degenerative disease of her spine, pain, and limited motion.

15. The VBT tethering device was approved by the Food and Drug Administration ("FDA") on August 16, 2019.

16. On March 4, 2020, Anthem denied R.M.'s claim for VBT as Investigational, based on Anthem's determination "[t]his procedure is not approvable under the plan clinical criteria because there is no proof or not enough proof that it improves health."

17. In making this determination, Anthem relied on its VBT Medical Policy.

18. On March 13, 2020, R.M.'s mother requested an expedited appeal of Anthem's denial, submitting a treatment narrative, peer reviewed article, and article regarding the FDA's approval of VBT.

19. On March 19, 2020, and again on April 19, 2020, Anthem upheld its decision to deny R.M.'s claim for VBT.

20. On May 4, 2020, R.M. submitted a request for her complete claim file to Anthem.

21. On May 15, 2020, R.M. timely submitted her second level appeal to Anthem.

22. Follow-up requests for R.M.'s claim file were forwarded to Anthem on May 14, 2020, June 3, 2020, June 17, 2020, July 1, 2020, July 24, 2020.

23. On July 29, 2020, Anthem provided R.M. with an incomplete copy of her claim file, 86 days after her initial request.

24. After multiple follow-up requests for the missing documentation in R.M.'s claim file, Anthem provided additional information to R.M. on August 21, 2020, September 1, 2020, and September 14, 2020. Each disclosure was incomplete.

25. On July 4, 2020, R.M. received an explanation of benefits ("EOB") from Anthem denying her claim for her surgical stay due to lack of prior authorization, even though the prior authorization request was submitted, and denied by Anthem on March 4, 2020 and was appealed by R.M. on May 15, 2020.

26. On September 1, 2020, R.M. timely filed her appeal of the July 4, 2020 EOB denial.

27. On October 30, 2020, R.M. supplemented her appeals with her complete medical and surgical records from two hospitals, two treatment narratives from her treating and

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