ASSISTANT SECRETARY OF DEFENSE
WASHINGTON, D. C. 20301

NOV 30 1983

HEALTH AFFAIRS

BEFORE THE OFFICE, ASSISTANT

SECRETARY OF DEFENSE (HEALTH AFFAIRS)

UNITED STATES DEPARTMENT OF DEFENSE

Appeal of	)	
	)	
Sponsor:	)	OASD(HA) File 83-28
	)	FINAL DECISION
SSN:	)	

This is the FINAL DECISION of the Assistant Secretary of Defense (Health Affairs) in the CHAMPUS Appeal OASD(HA) case file 83-28 pursuant to 10 U.S.C. 1071-1089 and DoD 6010.8-R, chapter X. The appealing party in this case is the beneficiary, the 13-year-old daughter of an active duty enlisted member of the United States Air Force, as represented by the CHAMPUS sponsor.

The appeal involves a question of CHAMPUS coverage of testing provided from July 8, 1980, to July 25, 1980, and hospitalization from July 15, 1980, to July 31, 1980. The total charge incurred by the beneficiary for the testing services was $325.00. The total hospital charge for the dates of hospitalization was $2,762.60. Although the CHAMPUS Fiscal Intermediary initially denied coverage of both the testing and hospitalization, upon appeal the claim for hospitalization was paid by the fiscal intermediary. Following further appeal, OCHAMPUS reversed the fiscal intermediary determination and denied coverage of the inpatient care and the testing. The sponsor was informed that cost-sharing of the hospitalization was in error, and recoupment of those funds was requested on the basis that the hospital care was investigational and thus excluded under CHAMPUS.

The hearing file of record, the tapes and oral testimony presented at the hearing, the Hearing Officer's Recommended Decision, and the Analysis and Recommendation of the Director, OCHAMPUS, have been reviewed. The amount in dispute is $3,087.60. It is the Hearing Officer's recommendation that CHAMPUS coverage for inpatient care and professional testing services from July 8, 1980, to July 31, 1980, be denied because the hospital care and professional services were for minimal brain dysfunction and thus excluded from coverage under CHAMPUS. The Director, OCHAMPUS, recommends partial adoption and partial rejection of the Recommended Decision.

Under DoD 6010.8-R, chapter X, the Office, Assistant Secretary of Defense (Health Affairs), may adopt or reject the Hearing Officer's Recommended Decision. In the case of rejection, a FINAL DECISION may be issued by the Assistant Secretary of Defense (Health Affairs) based on the appeal record.

After due consideration of the appeal record, the Acting Principal Deputy Assistant Secretary of Defense (Health Affairs) acting as the authorized designee for the Assistant Secretary, rejects the Hearing Officer's Recommended Decision insofar as it found the hospital treatment to be non-experimental and thus medically necessary and appropriate medical care. It is the finding of the Assistant Secretary of Defense (Health Affairs) that the Hearing Officer's Recommended Decision, as regards his findings that the treatment was non-experimental, does not reflect proper evaluation of the evidence or consideration of applicable regulations. The Assistant Secretary of Defense (Health Affairs) specifically concurs with the findings of the Hearing Officer that the hospital services and the services provided by the reading specialist were for minimal brain dysfunction and thus are excluded under CHAMPUS.

The FINAL DECISION of the Assistant Secretary of Defense (Health Affairs) is, therefore, to deny CHAMPUS coverage of the appealing party's inpatient care and professional services received from July 8, 1980, to July 31, 1980. The decision to deny CHAMPUS coverage of the claims is based on findings that such care was both experimental and related to minimal brain dysfunction, and are specifically excluded from coverage under CHAMPUS.

FACTUAL BACKGROUND

The beneficiary, a 13-year-old girl at the time of the care in question, had a history of chronic problems with hyperactivity, learning disability, and perennial rhinitis. From a statement submitted by the sponsor, the beneficiary had approximately 90 recorded doctor visits plus numerous medication refills in the 7 to 8 years prior to the care under appeal. She was tested for allergies at Air Force Base, at Army Medical Center on two occasions, and Army Hospital in in the past 5 years. At each of these facilities, the traditional scratch test was used to identify any sensitivity to pollens, dust, pets, etc. In addition, she was prescribed allergy shots which were routinely given at base clinics. This treatment, however, did little to relieve her condition, and she began having reactions to the shots. Although the sponsor requested the military allergist to test for food allergies, he refused or declined; instead he prescribed allergy diets. These diets consisted of withdrawing certain foods for a period and then overloading the beneficiary's system with the withdrawn foods and recording the results. The sponsor indicated that the beneficiary experienced several severe respiratory reactions which required emergency injections of epinephrine. Eventually the allergy shots were reduced and finally discontinued.

The allergist, , M.D., examined the beneficiary and made a diagnosis which included allergies, perennial nasal; attention deficit disorder; and susceptibility to chemicals in the environment manifests as emotional labilitv. He referred the beneficiary tc the Environmental Care Unit, Medical Center, ' , , for clinical ecological testing. At the hearing, Dr. testified that he made the referral to delineate the role of chemicals in food in the beneficiary's environment. Dr. further testified that, prior to his examination, the beneficiary's medical history included a psychiatric course of care for approximately one year and an indication that the patient was experiencing auditory problems. According to Dr. , the beneficiary had been on a drug regimen, including three drugs that were prescribed for minimal brain dysfunction in children. Although it was not the only reason, Dr. testified that his referral of the patient to the Environmental Care Unit of the hospital was in part due to the history of organic brain syndrome and his concurrence with that diagnosis. However, he emphasized that treatment in the Environmental Care Unit encompassed the beneficiary as a whole person, treating the totality of her person.

The attending physician during the hospitalization was . , M.D. Dr. submitted for the record a "Draft Case Report" pertaining to the beneficiary, entitled "Learning disabilities evaluated by multiple phase testing of multiple single-food direct challenges." The report contains the following information:

> "[The patient] is a 13 y.c. WF 8th grade student who at age 4-5 was noted to have hyperactivity. Initial treatment with Cylert (pemoline) was only partly effective, so she was shifted to Ritalin (methylphenidate) with definite improvement in her activity levels, and was maintained on this drug for 6 years. When she was 12, her playmates were usually aged 8 to 10. At school, she felt everyone was picking on her, calling her names, and bothering her in other ways that made her very angry. She was noted to have crying outbursts both in school and at home. In the year before admission, her parents noted she would ask them to repeat what they had said, and was constantly asking 'What?' School performance indicated continued difficulties with learning processes.
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> She complained of frequent headaches and stomach aches [sic], and had perennial rhinitis, with a spring-time exacerbation. Skin testing done 4 years earlier showed positive skin tests to milk, mold, trees, weeds, grass, cat and dog. The resulting immunotherapy considerably improved nasal

symptoms until it was stopped 1 year ago because of progressive local reaction severity. The mother had asthma, the grandmother hay fever, and there was a family history of food allergy. The child had had food allergy diagnosed in infancy, and the mother suspected that some foods triggered some of the emotional outbursts.

"For the above reasons, she was referred to us for evaluation of learning skills and possible relationship of learning deficits to 'allergic' factors.

"DEVELOPMENTAL HISTORY:

"Pregnancy and delivery were uneventful. After breast feeding for two weeks, she was put on a soy formula and then regular milk. The formula changes were made because of constant crying, colicky behavior, projectile vomitting, and rash. As a child she had nightmares and 'night terrors.' Her urethra was dilated at age two. She had asthma for two or three years. Also she had recurrent strep infections, frequent bouts of the 'flu,' recurrent sinus infections, and frequent headaches.

"Her motor and language development were considered on time, but in first grade the parents noted that she wrote upside down, backwards, and diagnonally. Parents were initially told nothing was wrong, but in grades two through four she was put in speech therapy. Beginning in fourth grade, she was followed by the school social worker for difficulty relating to peers, and crying spells in class. Later, she was taken out of the regular gym class because her coordination was so poor she could not compete with her peers, and she was placed in a special class.

"METHOD OF EVALUATION: AVOIDANCE PHASE

"To evaluate the possibility of environmental factors affecting learning disability, this patient was placed in the Environmental Care Unit, a facility designed to maximally reduce the impingement of organic inhalants (pollen, dusts, danders, molds etc.) as well as inhalant chemicals such as smog (air is ducted in through particulate, potassium permanganate and

charcoal filters) and outgassing components from interior surfaces and furnishings. Patients placed in this facility are put on a fast to reduce oral exposures, and kept on non-chlorinated water, to reduce the number of types of chemical entities in the water. None of these factors are certainly known to cause difficulty for specific patients, but it is felt that if by chance they remain exposed to something to which they are sensitive, they would show no change in symptoms and the hypothesis can not [sic] be evaluated. If symptoms improve, the patient goes into a challenge phase.

"CHALLENGE PHASE:

"Challenges were conducted as follows: Patient was fed a single food per meal, at approximate 4 hours intervals. About 30 minutes after each challenge, her mother tested her for visual distractibility (VISD), auditory memory (AM) (the Detroit scale), oral reading (OR) (Gray Oral form B) and Fine Motor Speed and Accuracy (FM) (Detroit Motor Speed and Precision scale). These tests were not always done in the same sequence. Evaluation of test scores was in comparison with testing of the preceding and succeeding days to compare within the obvious 'practice effect.'

"At the end of three days of this regimen, her mother noted that she had almost entirely stopped asking 'what?' when spoken to, but she did show considerable fatigue (perhaps related to the ketosis of fasting). At this point she was tested by one of us, using the same basic tests, but Gray Form D instead of B. Subsequently, she was given the full battery of tests 60 minutes after each meal by her mother. . . . "

Prior to the beneficiary receiving the care at this facility, the sponsor requested and received a statement of nonavailability indicating that environmental desensitization care was not available at the local military treatment facilities. This statement of nonavailability was issued by the United States Air Force Clinic at Air Force Base. In addition to the hospitalization, it was decided to elicit the aid of a reading specialist to determine if food allergies were causing the beneficiary's learning problems. The reading specialist was to correlate the various sensitivities to challenged stimuli such as food, gasoline, etc., with the academic performance of the

beneficiary. The hypothesis was that some stimuli would affect the beneficiary negatively resulting in decreased motor skills, physiological complaints, visual distractibility, increased difficulty with word pronunciation, and lack of smoothness.

The "Draft Case Report" submitted by Dr. indicates that the beneficiary was seen 4 days after discharge and that she had not had any of her usual headache, stomachache, or leg pain. Although she was again saying "what?", it was infrequent and her mother indicated the beneficiary was able to tolerate her younger brother's teasing with much more equanimity. Three months after discharge, the patient was reported to be doing better in school, but this was only very general in nature.

Subsequent to her hospitalization, immunotherapy was restored using the inhalent serums provided by Dr. office. According to the sponsor, the beneficiary has taken her anti-sensitivity serum and lives a relatively normal teenage existence. In addition to her improved medical condition, a dramatic improvement in academic areas has been achieved with an increase in grade average from "C" to "A-". According to the sponsor, his daughter "went from a teary-eyed problem child unable to get along with her peers to a fairly well adjusted and integrated member of her school class."

The reading specialist filed a participating claim with the CHAMPUS Fiscal Intermediary for reading disability evaluation in the amount of $325.00. The diagnosis listed on the claim form was "Learning disability of probable organic nature with findings consistent with that of Minimal Brain Dysfunction." The hospital filed a claim with the CHAMPUS Fiscal Intermediary for the 16-day period of hospitalization from July 15, 1980, to July 31, 1980 in the amount of $2,762.60. The diagnosis listed on the hospital claim form was "Specific delays in Development; Other Specific Learning Difficulties." The CHAMPUS Fiscal Intermediary denied the claim of the reading specialist on the basis that the services which this reading specialist rendered were not benefits under CHAMPUS. The CHAMPUS Fiscal Intermediary also denied the claim of the hospital on the same grounds.

The claim for the reading specialist was submitted for informal review by the fiscal intermediary. As a result of that review, the fiscal intermediary once again denied benefits on the basis that the treatment was for minimal brain dysfunction which is specifically excluded under CHAMPUS. The fiscal intermediary also pointed out that the original diagnosis indicated minimal brain dysfunction.

With respect to the hospital charges, the fiscal intermediary reversed the initial decision and determined that the hospital portion of the charges was subject to CHAMPUS cost-sharing. Because of the reversal of position concerning the hospital care, the sponsor requested that the fiscal intermediary again review the denial of the services for the reading specialist. After a review of the file, the fiscal intermediary once again determined

that CHAMPUS could not cost-share in the services provided by the reading specialist on the basis that the professional staff psychiatric consultant of the fiscal intermediary believed that this type of care was experimental.

On July 7, 1981, the sponsor appealed to OCHAMPUS. In the process of the First Level Appeal determination by OCHAMPUS, the case file was forwarded to the Medical Director, OCHAMPUS, for review.

In the opinion of the Medical Director, the care was primarily for the evaluation and amelioration of the child's learning disability. In addition, the services were considered primarily investigational and not in accordance with accepted medical practice. Based on this opinion, the OCHAMPUS First Level Appeal decision denied CHAMPUS cost-sharing of the 16-day period of hospitalization from July 15, 1980, through July 31, 1980, as well as the claim for the reading specialist.

The sponsor requested a hearing which was held by Sherman R. Bendalin, Hearing Officer, on March 2, 1983. The beneficiary was not represented by counsel at the hearing. The Hearing Officer has submitted his Recommended Decision and all prior levels of administrative review have been exhausted. Issuance of a FINAL DECISION is proper.

ISSUES AND FINDINGS OF FACT

The primary issue in this appeal is whether the inpatient care received at Hospital from July 8, 1980 to July 31, 1980, and the professional services provided by the reading specialist are authorized care under CHAMPUS. In resolving this issue it must be determined (1) whether the care and services provided during the period in issue are services and supplies related to minimal brain dysfunction and thus excluded from coverage, and (2) whether the care rendered during the period in issue was medically necessary and appropriate medical care.

Learning Disorder

The CHAMPUS regulation, DoD 6010.8-R, chapter IV, G.32., specifically excludes from CHAMPUS coverage:

> "Minimum Brain Dysfunction. Services and supplies related to minimum brain dysfunction (MBD), also sometimes called Organic Brain Syndrome, Hyperkinesis, or Learning Disorder."

Although the appealing party, through her representative, and the referring physician argue that the care in this case was not primarily for a learning disorder, the weight of the evidence is to the contrary. The diagnosis listed on the reading

specialist's claim was "Learning Disability of probable organic nature with findings consistent with that of Minimum Brain Dysfunction." Similarly, the diagnosis on the hospital claim included "Specific Delays in Development; Other Specific Learning Difficulties." Perhaps more important, however, is the "Draft Case Report" submitted by the attending physician during the hospitalization which is entitled "Learning disabilities evaluated by multiple phase testing of multiple single-food direct challenges."

The OCHAMPUS Medical Director reviewed the record and noted that the patient had been treated on an outpatient basis by a psychiatrist for over-anxious reaction of childhood (DSM II 308.2) in 1977-78. In the opinion of the Medical Director:

> "This therapist, while ascertaining a primarily psychological causology to symptoms of sadness and irritability - which he observed were in synchrony with similar mood fluctuation in the patient's mother who was in psychiatric treatment, nevertheless placed the child on Cylert, a psychostimulant medication frequently used in the treatment of Attention Deficit Disorders (i.e., Minimal Brain Dysfunction), and noted an improvement in her symptoms. No conclusions are noted that would have attributed her improvement to the sole or mutual influences of medication or psychotherapy. . . ."

This opinion was supported by the referring physician's testimony at the hearing that prior to his examination of the patient she had been on a drug regimen including three drugs prescribed for minimal brain dysfunction in children. In addition, the referring physician testified that one of the reasons, although not the only reason, for referral to the hospital's Environmental Care Unit was the history of minimum brain dysfunction and his concurrence, based on the medical history, with that diagnosis.

Finally, the referring physician attempted, while testifying, to minimize the significance of the minimal brain dysfunction as concerns the hospitalization by stating that the hospitalization was intended to encompass the beneficiary as a whole person and to treat the totality of her person. In the absence of information to the contrary, the referring physician's testimony is consistent with the following opinion of the OCHAMPUS Medical Director:

> "The hospitalization - while likely motivated by concern for the patient's multiple allergic, learning, and emotional symptoms - was primarily for the evaluation and amelioration of the child's learning difficulties. This is clearly stated by the

> physician and reading specialist, who were hoping to provide clinical substantiation of their theory that such environmental allergies as contained in foods and other substances, can affect learning through disturbances in brain functions affecting perception and information processing - thus affecting intellectual - cognitive functions. . . ."

The Hearing Officer found that based on the totality of the evidence, the beneficiary was hospitalized for treatment of a history of ailments described as a learning disorder or learning disability. I concur in that finding and adopt it as the decision of the Acting Assistant Secretary of Defense (Health Affairs). Therefore, it is my determination that the claim for hospitalization from July 15 to July 31, 1980, and the claim for the services of a reading specialist are denied because services and supplies related to minimal brain dysfunction or learning disabilities are specifically excluded from CHAMPUS coverage.

Medical Necessity/Appropriate Level of Care

The Department of Defense Appropriations Act, 1980, Public Law 96-154, prohibits the use of CHAMPUS funds for ". . . any service or supply which is not medically or psychologically necessary to prevent, diagnose or treat a mental or physical illness, injury, or bodily malfunction assessed or diagnosed by a physician, dentist, [or] clinical psychologist . . ." This restriction has consistently appeared in each subsequent Department of Defense Appropriation Act.

The CHAMPUS regulation DoD 6010.8-R, chapter II, B.104., defines medically necessary as:

> ". . . the level of services and supplies (that is, frequency, extent, and kinds) adequate for the diagnosis and treatment of illness or injury . . . . Medically necessary includes concept of appropriate medical care."

"Appropriate Medical Care" is defined in DoD 6010.8-R, chapter II, B.14., in part, as follows:

> "a. That medical care where the medical services performed in the treatment of a disease or injury, . . . are in keeping with the generally acceptable norm for medical practice in the United States, . . ."

In addition, the CHAMPUS regulation, DoD 60108-R, chapter IV, G., specifically excludes from coverage:

> "14. Study, Grant or Research Program. Services and supplies provided as part of or under a scientific or medical study, grant, or research program.
>
> 15. Not in Accordance with Accepted Standards. Services and supplies not provided in accordance with accepted professional standards; or related to essentially experimental procedures or treatment regimens."

To constitute a CHAMPUS covered service, then, the clinical ecology course of medical care must be adequate for the diagnosis and treatment of illness or disease and, correspondingly, constitute a treatment of a disease or illness. As previously determined in this case, the beneficiary was hospitalized in July 1980 for treatment of minimal brain dysfunction or learning disorders. Even if services related to learning disorders were not specifically excluded from CHAMPUS coverage, the acceptance and efficacy of the treatment of learning disorders by the clinical ecology course of medical care must be established before CHAMPUS could consider it medically necessary and appropriate care.

The Hearing Officer found that the clinical ecology course of medical care undergone by the beneficiary in this case was not experimental, but was indeed appropriate care. After reviewing the entire record, I must reject the Hearing Officer's finding that the care in question is not investigational nor a clinical study. I reject the Hearing Officer's finding as not reflecting proper evaluation of the evidence or consideration of the applicable regulation and previous FINAL DECISIONS of this office regarding investigational procedures.

The issue of investigational procedures has been addressed most recently in cases involving cardiac rehabilitation exercise programs. FINAL DECISIONS in those cases established criteria for determining care to be investigational or not medically necessary as the lack of medical documentation, authoritative medical literature, and recognized professional opinions sufficient to establish the general acceptance and efficacy of the program at the time the care was received. See OASD(HA) Case Files 01-81 and 83-16.

After reviewing the file in this case, the OCHAMPUS Medical Director opined that the clinical ecology was investigational in nature. After noting the medical history of the patient prior to the hospitalization in question, the Medical Director opined that:

> "The tie was apparently made between the child's attention-deficit disorder, emotional problems, and learning difficulties, and attributed in toto to her allergic

tendencies. This trend - correlating psychological and other problems to allergies to environmental substances - is a controversial one. It has resulted in the opening of several 'environmental' or 'ecology' inpatient facilities in the U.S. by a number of adherents to this theory. The American Academy of Allergy has not endorsed this form of treatment and the Foundation for Medical Care has advised OCHAMPUS that such treatments are not considered a standard of care, but rather, would be considered 'investigational'. OCHAMPUS has repeatedly questioned claims and preauthorization requests from such centers. Therefore [I] would consider on this basis, that the care provided - while it may or not have benefited the patient - cannot be considered medically necessary in the treatment of the allergic conditions. Moreover, the lack of adequate documentation that all outpatient evaluation and treatments had been unsuccessfully tried lends support to the contention that inpatient treatment would have been, not only of questionable medical necessity, but also medical appropriateness.

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"Review of the records indicates that the hospitalization was primarily concerned with evaluation - through controlled allergen challenges and correlated learning effects - and with patient-family education, rather than a specific course of desensitization treatments. Desensitization would involve a course of injections of graduated doses that would allow progressive immunity to be developed to the substances. If such treatments occurred, [the OCHAMPUS Medical Director] has not gleaned evidence of them from the record. It appears the "treatments" would have been considered to be the avoidance of identified allergenic foods and other substances, following discharge from the hospital. Thus, the hospitalization was not primarily focused on treatment, per se, but on the identification of allergenic substances to the investigators and the parents.

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". . . [T]he allergic testing was conducted as a clinical investigational study which attempted to establish documentation for a theoretical tie between learning problems, as a neurophysiological function, with systemic immunophysiologic sensitivity to such apparent allergic substances as foods. The investigators indicate that such findings as were evidenced in this evaluation had not previously been documented in the medical literature through other clinical research studies. This clearly spells out the investigational nature of the evaluation."

The Hearing Officer rejected the opinions of the OCHAMPUS Medical Director "as not persuasive since they are without corroboration or support whatsoever in the record." I find the Hearing Officer's statement in error.

The Hearing Officer acknowledged that although it "appears to be making medical headway," the clinical ecology course of care is not accepted by all parts of the medical community. The Hearing Officer failed to cite the medical documentation, authoritative medical literature, and recognized professional opinion upon which he relies to establish the general acceptance and efficacy (at the time of the care in question) of the clinical ecology program in the treatment of learning disorders. Rather, he rejects without comment the Medical Director's statement that the American Academy of Allergy does not endorse this treatment and the Colorado Foundation for Medical Care opinion that such treatments are not considered a standard of care, but are considered investigational.

I find the opinions of the OCHAMPUS Medical Director to be supported by the case file in this hearing. While the Hearing Officer may have found the referring physician's testimony persuasive, the most credible evidence on the issue of investigational care would appear to be the statements and reports submitted by the treating physician, Dr. . By letter dated February 22, 1981, Dr. furnished a copy of the "Draft Case Report" resulting from the treatment of the appealing party. In addressing the initial denial of the beneficiary's claim, Dr. ' letter states, in part:

"[S]ince the evaluation was of the brain and its apparent malfunctions, there appears to be a question about its medical relevance . . . . [T]he reason for this question is that brain allergy is not

> uniformly recognized, and etiologic relationship of environmental substance to disorders of learning function is not yet generally appreciated. This is not surprising! Although multiple reports are in the literature and our own experience with several cases in the past has suggested improvement by the control of environmental factors, [the beneficiary's] case was the first one we felt was adequately measured to report in the literature."

The "Draft Case Report" further documents and supports a finding that the clinical ecology treatment of learning disorders, at the time of the care in question, was investigational. The discussion section of the report contains the following:

> "This case report has weaknesses which keep it from being solid evidence that in one individual, specific foods can trigger specific defects in mental processes, as measured by standardized test performance. First because only one of the substances 'identified' was repeated, and then in unblinded fashion, so if the subject had any reason to, she could have easily biased the results. The second weakness is that repetitive testing on the same test instrument was not considered in the design of the tests being used, so there is a 'practice effect' operating. The AM strongly showed practice since it continued upward throughout. Other tests administered after challenge were done by the patient's mother, someone only briefly trained in this type.
>
> On the other hand, since the etiology of the 'dysfunction' in MBD is not understood, it is quite reasonable to consider the <u>possibility</u> that it could come from exposures to unrecognized triggering agents, including inhalant allergens, inhalant chemicals, and foods. Food 'allergy' is recognized as being an infrequent, but clear cause of a variety of symptoms of other types, so it is conceivable it could be operant here. . . .
>
> <u>To our knowledge this kind of avoidance of foods followed by direct challenge has not been previously reported in patients with L.D. symptoms.</u> (emphasis added) Despite the problems cited above, the improvement from before hospitalization and after avoidance was definite and consistent in all parameters measured, and was done by a competent and

experienced examiner. The decrement in performance on re-challenge with an implicated food was similarly measured by the same examiner. On measurements done by an [in experienced] examiner, the patient's mother, there were clear drops from the rising curve of scores through the hospitalization, which would probably not represent changes in technique, so suggest 'real' changes as they are clearly below the curve established.

"Each case of a patient studied in a new way represents a learning experience for those doing the study. We feel we have learned a number of lessons which will be helpful in attempting to establish more solidly whether this method might be a rational and viable way of assessing children with this type of problem. (emphasis added)

"1. Standardized testing is necessary to establish a baseline against which to compare adverse effects of repeated challenges and retesting. On several challenges, there was no outward sign of emotional or other symptoms. Without the requirement to perform, the changes would have been entirely unrecognized.

"2. Testing must incorporate a number of parameters. On one challenge, the adverse effect was in visual distractibility (a physiological or neurological measurement), on another in oral reading (an academic measurement) and yet another in Fine Motor Speed but more often Accuracy (a visual-motor measurement). In one other instance, clear emotional changes were unaccompanied by any measureable changes in standardized test performance.

"3. We need a wider spectrum of tests available. This patient had a history of clumsiness and diminished coordination, yet we did not have any measurement of gross motor performance. We also did not have any test of learning per se, such as the type suggested by Swanson.

"4. Some better ways of handling the 'practice effect' are needed. On this patient the practice effect removed one test entirely from our battery. One approach to

> this will be to try to have additional iterations of the same type of material, so that even though there is a practice effect for each iteration, the cumulative memorization may be low enough to retain some flexibility in the testing.
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> "We also have no indication how common (or rare) this type of patient might be. Her history has features in common with many others of her generation, labeled MBD, LD, hyperactive, organic brain syndrome, specific learning disorder, but there may be manly (sic) unrecognized differences. We are planning to undertake a pilot study of an additional similar 25 patients with the aim of learning whether these findings appear in other individuals, and with the intent of sharpening our perceptions of the individual being tested and the breadth, accuracy and reproducibility of the replicated tests."

In view of the above, it would appear the treating physician was aware, at the time of care, that the general acceptance and efficacy of the care in question had not been established by medical documentation, authoritative medical literature, and recognized professional opinion.

Although the Hearing Officer believed the record clearly demonstrates the salutary effects of the inpatient care, such is not a determinative factor concerning the issue of medical necessity and appropriate care. I am constrained by regulatory authority to authorize benefits only for services which are generally accepted in the treatment of disease or illness. After reviewing the entire record, I find that the appealing party failed to establish the medical necessity or appropriateness of the clinical ecology treatment of learning disorders. Therefore, I must deny CHAMPUS coverage of the beneficiary's claim for inpatient care from July 15 to July 31, 1980, and the claim for services of the reading specialist.

SUMMARY

In summary, from the record in this appeal, I find the beneficiary's clinical ecology program not to be medically necessary in the treatment of minimal brain dysfunction or learning disorders based on the lack of medical documentation, medical literature, and recognized professional opinion sufficient to establish the general acceptance and efficacy of the program at the time the services were received. I further find that claims under appeal involved the treatment of a learning disorder and are specifically excluded from CHAMPUS coverage. Therefore, the beneficiary's appeal and her claims for hospitalization from July 15 to July 31, 1980, and the services of a reading specialist are denied. The Director, OCHAMPUS, is

directed to review the claims records and take appropriate action under the Federal Claims Collection Act to recover any erroneous payments that may have been made in this case. Issuance of this FINAL DECISION completes the administrative appeals process under DoD 6010.8-R, chapter X, and no further administrative appeal is available.

Vernon McKenzie
Acting Principal Deputy Assistant Secretary