

PRIMARY ISSUE IN DISPUTE

The primary matter at issue in this case is whether the 107 hospital emergency room visits for the purpose of receiving injections of Demerol for relief of migraine headache constituted care which was appropriate, essential and medically necessary and in keeping with generally acceptable norms for medical practice in the United States.

The applicable regulation for the services performed prior to 1 June 1977 is Army Regulation AR 40-121 which defines medically necessary as those services "...essential for the care of the patient or treatment of the patient's medical or surgical condition." (Reference: Army Regulation AR 40-121, CHAPTER 1, Section 1-3, c.) That regulation further authorizes benefits only for "...types of care ...which are generally accepted as being part of good medical practice..." (Reference: Army Regulation AR 40-121, Chapter 5, Section 5-2)

For the services provided after 1 June 1977 CHAMPUS Regulation DoD 6010.8-R is applicable. It defines medically necessary as "...the level of services and supplies (i.e. frequency, extent and kinds) adequate for the diagnosis and treatment of illness or injury ... [which] includes concept of appropriate medical care." (Reference: CHAMPUS Regulation DoD 6010.8-R, Chapter II, Subsection B. 103) The current CHAMPUS Regulation defines appropriate medical care as "...medical services performed in the treatment of a disease or injury ...[which] are in keeping with the generally acceptable norm for medical practice in the United States." (Reference: CHAMPUS Regulation DoD 6010.8-R, Chapter II, Subsection B. 14.) This Regulation also specifically excludes services and supplies "...not provided in accordance with accepted professional standards." (Reference: CHAMPUS Regulation DoD 6010.8-R, Chapter IV, Subsection G. 16.) This Regulation further states "...CHAMPUS benefits cannot be authorized to support and/or maintain an existing or potential drug abuse situation..." (Reference: CHAMPUS Regulation DoD 6010.8R, Chapter IV, Subsection E. 11.)

The Appealing party, her spouse and her attending physician, all submitted testimony and statements detailing factors which in their view, supported the position that the administration of injections of Demerol for migraine represented necessary and appropriate care and that drug abuse, either actual or potential, was not a problem in this case. Nonetheless it is the finding of the Principal Deputy Assistant Secretary of Defense (Health Affairs)

that the facts presented in this case do not support that position. In order to insure that the appealing party fully understands the bases upon which the initial denial is being reaffirmed and upheld, each of the points at issue is addressed in this FINAL DECISION.

1. Demerol Injections for Migraine Headache: Inappropriate Care. The appealing party, sponsor and attending physician all claimed that the patient had a long history of migraine headache for which various methods of treatment were attempted without satisfactory results and that Demerol injections were necessary to relieve the headaches during severe attacks. It was further claimed that Demerol injections had been prescribed as required since 1963 at both Uniformed Service and civilian facilities. (Except for personal statements from the appealing party and her sponsor/spouse, no evidence was presented to support the claim that Demerol was actually prescribed prior to 1972.) In 1972 the appealing party became the patient of the current attending physician.
 - o Diagnosis of Migraine Headache. The attending physician maintained that the existence of migraine headaches in this patient was well substantiated and he took strong exception to the Program doubting the presence of the migraine headaches, apparently implying that if the migraines actually occurred, there should be no further question about CHAMPUS benefits. He stated that the migraine symptoms had been present for more than twenty (20) years and that when he assumed the responsibility for the patient in 1972, she had already been receiving Demerol injections for migraine. First, it is assumed that the attending physician based his diagnosis of migraine on symptoms revealed by the appealing party since he presented no evidence that any diagnostic studies were performed from the onset of his management of the case in 1972 until the patient was referred for a neurological consultation in March 1976. With no indication that diagnostic studies were performed during this four (4) year period, it would not be unreasonable to question whether some condition other than migraine was, in fact, causing the headaches. However, this is a moot point because whether or not the migraine headaches actually occurred was never questioned in this case. Rather the matter at issue is the continued long term use of Demerol injections specifically in connection with migraine--i.e., the

disputed medical services were denied because it was determined that the Demerol injections represented inappropriate treatment for migraine. Therefore, it is difficult to ascertain why the attending physician raised this issue. (Reference Army Regulation AR 40-121, Chapter 5, Section 5-2; CHAMPUS Regulation DoD 6010.8-R, Chapter II, Subsection B.14 and B.103, and Chapter IV, Subsection G.16)

- o Difficult Management Case. The attending physician further claimed that the appealing party's condition was difficult to manage and [again implying] that because of this, the use of Demerol injections was therefore appropriate. That the appealing party was considered a management problem was confirmed by the consulting neurologist in 1976 who identified multiple physical problems including primary bronchiectasis, history of pneumothorax, history of ovarian cysts, multiple gynecological surgical procedures for spontaneous abortions, and finally in 1970, a hysterectomy and anterior vaginal repair. There was also anecdotal evidence presented indicating that emotional and mental disorders were present and that a psychiatric consultation was recommended and performed. (It is noted, however, that results of the evaluation were not submitted for the Hearing File of Record, nor was information regarding any suggested psychiatric treatment plan made available.) Again, the fact that the patient presented a difficult management problem was never questioned. What is at issue is how her case was managed. The presentation of a patient with the described difficulties, including acknowledged mental problems, requires particular caution in developing a treatment plan. At a minimum it would indicate a need to avoid any medications which might further contribute to the management problem. The fact that the appealing party did present a difficult management situation supports and reinforces the Program's decision that the long term use of Demerol injections was inappropriate. (Reference: Army Regulation AR 40-121 CHAPTER 5 Section 5-2; CHAMPUS Regulation DoD 6010.8-R. Chapter II, Subsections B.14 and B.103, and CHAPTER IV, Subsection G.16)

- o Alternative Therapies. The Hearing File of Record and the oral testimony clearly indicate that the primary form of treatment offered by the attending physician was injections of Demerol. At the hearing it was claimed that other therapeutic measures had produced either adverse reactions or poor results, again implying that Demerol injections were therefore appropriate. The only information presented that alternative therapeutic regimens were ineffective or produced an adverse reaction, was apparently based on personal statements of the appealing party. The Hearing File of Record indicates there were a few secondary therapeutic medications infrequently recommended (by someone other than the attending physician), but the appealing party did not cooperate; therefore, these were not used consistently. Biofeedback was recommended and tried but the appealing party's participation was erratic and although some benefits were reported, she still received the Demerol injections whenever she requested them. It would appear that because the Demerol was available on request, the ultimate failure of alternative therapies was predestined, whatever they might be because there was little incentive for the patient to gain the full effect of any other forms of therapy. Further, the use of Demerol was essentially a palliative measure which did not treat the condition but offered only temporary pain relief. The consulting neurologist reported concern over the continued use of Demerol as did the clinical psychologist who conducted the Biofeedback; but the use of Demerol was continued even in view of these concerns, with little or no effort to seek out appropriate alternative therapies. We disagree with the Hearing Officer's position that other therapies were tried and therefore benefits should be extended for the Demerol injections. First, his finding was not based on conclusive evidence that alternative therapies (other than the Biofeedback program) were actually tried. Second, even if this is an accurate assumption, it has no bearing the specific question of whether the Demerol injections represented appropriate care. The fact that the appealing party was not anxious to try other therapeutic approaches or that the attending physician was willing to accept her personal statement concerning prior results of other medications does not change the finding that long term use of Demerol injections for migraine is not in keeping

with generally acceptable norms for medical practice in the United States. (Reference: Army Regulation AR 40-121 CHAPTER 5 Section 5-2, CHAMPUS Regulation DoD 6010.8-R Chapter II, Subsections B.14 and B.103, and Chapter IV, Subsection G. 16).

- o Demerol as the Drug of Choice. There is also some evidence that Demerol was not a proper choice of medication for this patient's migraine headache syndrome for reasons other than the fact it is not a therapeutic regimen and has a potential for abuse. Demerol has an inherent capacity to elevate cerebrospinal fluid pressure. In early 1972 skull Xrays identified increased cerebral pressure as a possible problem but there was no evidence in the Hearing File of Record that this finding was investigated further. Considering that Demerol could increase the cerebrospinal fluid pressure even more, its use may have contributed to the duration of the headache episodes. This possibility is an additional reason why Demerol was inappropriately used in this case. (Reference: Army Regulation AR 40-121, Chapter 5, Section 5-2; and CHAMPUS Regulation DoD 6010.8-R, Chapter II, Subsection B.14 and Chapter IV, Subsection G.16).

- o. Not Generally Accepted Medical Practice. The Hearing File of Record contains statements from the consulting neurologist and the clinical psychologist expressing concern over the use of Demerol in this case. Further the medical review staff of the CHAMPUS Fiscal Intermediary immediately identified this case as one of inappropriate care. Subsequent reviews by consulting physicians and peer review groups concurred that the use of Demerol injections constituted inappropriate care. Therefore, despite the position taken by the appealing party, her sponsor/spouse and the attending physician, it is the finding of the principal Deputy Assistant Secretary of Defense (Health Affairs) that the long term, continued use of Demerol injections is not in keeping with the general professional practice in the United States for the treatment of migraine. Further, that any long term use of such a potentially addictive drug for a chronic, non-terminal condition must be considered generally inappropriate. (Reference:

Army Regulation AR 40-121, Chapter 5, Section 5-2, CHAMPUS Regulation DoD 6010.8-R, Chapter II, Subsection B.14 and B.103, and Chapter IV, Subsection G.16).

2. Potential for Drug Abuse. The attending physician steadfastly maintained that the appealing party had no drug addiction problem. Further, he insisted there was no potential for drug abuse. He presented no indication that the continued use of Demerol injections concerned him from the standpoint of possible dependency.
 - o Periods of Time without Demerol. The attending physician offered the fact that the appealing party was capable of going for long periods of time without Demerol as proof that she presented no drug dependency problem. It is true that during the period in dispute Demerol injections were not administered at the hospital on some days--sometimes no injections were administered for several days at a time. Statements were made that during other periods the appealing party went as long as 42 days without seeking Demerol injections. Since emergency rooms records for other than the period of time in dispute were not obtained, no verification of this latter claim is possible. However, even it is true, this cannot be considered conclusive since it is possible that other medications were utilized by the patient during intervening periods as she was known to have had at least Darvon available. It remains the Program's position that despite the fact that the appealing party may have gone without the Demerol injections for periods of time, the available evidence continues to be sufficiently compelling for a conclusion that a significant potential for drug abuse existed. (Reference: Army Regulation AR 40.12, Chapter 5, Section 5-2; and CHAMPUS Regulation DoD 6010.8-R Chapter IV, Subsection E.11 and G.16.)
 - o Demerol: Frequency and Duration of Use. Demerol has the capacity to produce addiction and a warning to this effect is made by its manufacturers. Continued use can produce a tolerance where increased and more frequent dosages are required in order to produce the desired effect. It is anticipated that even intermittent use of the drug will produce at least some degree of psychological if not physical dependency. For this reason it

is not an appropriate drug for long term use in chronic, non-terminal illness particularly where concomitant mental problems are also a factor. Despite the obvious contraindications in this case, it appears that for several years Demerol has been made available whenever the appealing party requested it. That the attending physician personally denied any potential for drug dependence existed does not overcome the weight of evidence that continued use of Demerol represented inappropriate care, with a strong potential for abuse. (Reference: Army Regulation AR 40-121, CHAPTER 5 Section 5-2; and CHAMPUS Regulation, DoD 6010.8-R Chapter IV, Subsection E.11 and G. 16)

- o Other Prescribed Medications Available. The Hearing File of Record substantiated not only that Darvon had also been prescribed and was available to the appealing party during the period in question, but that she had apparently also been using this medication on an ongoing basis for many years. On several occasions the emergency room records reported that Darvon had been taken prior to her visit to obtain the Demerol injection. If the attending physician was not the physician prescribing the Darvon, he was made aware of its use from the emergency room records he had to sign. Although the dosage and frequency of Darvon use was not revealed, anecdotal information would indicate it was readily available to the appealing party. Darvon is a drug which is currently undergoing intense public scrutiny as to whether it should be used at all (because of its potential for abuse). The manufacturer of Darvon provides a warning of possible addiction and about its additive effects when used in connection with other drugs. It's availability to the appealing party and use in combination with Demerol only increases the potential for a serious abuse problem. There was also some use of Valium reported. Use of this mood altering drug which also has a potential for dependency only further complicates the drug picture in this case. (It is noted that the attending physician made no comment whatsoever concerning the appealing party's use of other medications.) The dangers presented by the synergistic interaction of these drugs, the possibility of contributing to, rather than relieving, the headache syndrome, and the documented potential for abuse particularly in

a multiple use drug situation further reinforces the finding that the treatment was inappropriate and that a strong potential for drug abuse did, in fact exist.

(Reference: Army Regulation AR 40-121, Chapter 5, Section 5-2; and CHAMPUS Regulation DoD 6010.8-R, Chapter IV, Subsections E. II and 6.16).

- o Indications of Possible Drug Abuse. Despite the statements from the attending physician that the appealing party presented no potential for drug abuse, a review of the Hearing File of Record and oral testimony identifies the presence of certain factors that could indicate the problem is emerging or already exists. These include (but are not limited to) a history of short term inpatient stays with minimum diagnostic workup where the primary treatment modality was injection for pain; lack of patient interest in alternative therapies; refusal by the patient to accept recommended medication substitutes; pattern of patient negative response to alternative therapies; use of injections rather than the tablet form of Demerol; arrangements for Demerol injections to be available on patient demand rather than a physician-controlled regimen; use of hospital emergency room rather than personal contact with attending physician; concurrent use of Darvon, Valium and perhaps other potential dependency-producing drugs in addition to the Demerol injections; presence of a chronic, long term condition; minimal use of diagnostic studies and/or consultations; the period of time Demerol injections have been used (Hearing File of Record confirms for five years; appealing party claimed Demerol injections had been prescribed since 1963); the presence of mental problems, with a noted susceptibility to stress; and strong indications that the patient rather than the physician is in control of the treatment. While each of these factors in and of itself does not necessarily confirm the existence of a physical and/or psychological dependency, in the aggregate they are sufficiently compelling to support a finding that at a minimum a strong potential for drug abuse, if not actual dependency, existed. (Reference: Army Regulation AR-40-121, Chapter 5 Section 5-2; CHAMPUS Regulation DoD 6010.8-R, Chapter IV, Subsection E.11 and G.16.)

- o Issue of Drug Dependency. Despite the strong position taken by the attending physician that the appealing party presented no potential for drug abuse, it is the finding of the Principal Deputy Assistant Secretary of Defense that not only does such potential exist in this case, it is very likely a degree of drug dependency, either physical or psychological, has already occurred. (Although at the hearing the Assistant General Counsel representing CHAMPUS indicated that the matter at issue was not potential or actual drug abuse, this was in error. While drug abuse is obviously a separate issue, the potential for dependency is a major factor in professional opinion that Demerol injections for migraine are inappropriate.) The Hearing File of Record contains no evidence that contraindicates the Program's position that a potential for drug abuse did in fact exist in this case. (Reference: Army Regulation AR 40-121, Chapter 5, Section 5-2; CHAMPUS Regulation DoD 6010.8-R, Chapter IV, Subsections E.11. and G.16)

3. Use of Emergency Room Facilities. While the initial denial and Informal Review decision issued by the CHAMPUS Fiscal Intermediary cited misuse of the hospital emergency room as, a reason for denial, this is actually a sub-issue growing out of the fact that long term, frequent Demerol injections for migraine headache were found to be inappropriate medical care. However, notwithstanding it being a sub-issue, we do not concur with the Hearing Officers findings on this point. In this case, the emergency room was utilized as a source of primary medical care for non-emergency care. The records indicate that the patient was not in a state of crisis, arrived in an ambulatory state and presented no symptoms of critical illness other than headache. Her mode of arrival was always ambulatory and she was able to state her complaint. If the appealing party was not prescribed the drug of her choice, except for one occasion she refused it and left the emergency room. The emergency room staff routinely performed only a cursory review of blood pressure, pulse and other vital signs, then contacted the attending physician or one of his associates and administered the Demerol which were prescribed by telephone. On only one occasion during the period in dispute was the patient examined by the emergency room staff physician. The only reason presented for use of the emergency room was that the attending physician did not maintain Demerol

as part of his office supplies. It would appear that the use of the emergency room services was used as a substitute for the physician's office--primarily for the convenience of the physician. Use of the emergency room was not based on any medical necessity for the sophisticated services or level of care available in that setting. (Reference Army Regulation AR 40-121 CHAPTER 1 Section 1-3 c; CHAMPUS Regulation, DoD 6010.8-R, Chapter IV, Subsection B. 103)

SECONDARY ISSUES

Several secondary issues were raised which the appealing party, her sponsor and/or her attending physician claimed should receive special consideration and support the extension of CHAMPUS benefits for the Demerol injections.

1. Attending Physician Received No Fee. The attending physician claimed that since he charged no fee for prescribing the Demerol injections for the patient during her visits to the hospital emergency room that this [somehow] removed any question about the Demerol injections. It was his testimony that he would routinely order the necessary medications and would then sign the emergency room forms on a subsequent visit to the hospital. That he did not charge for such telephone prescribing cannot be considered unusual since emergency room records presented no evidence that any personal contact was made with the appealing party at the time of her visits to the emergency room. However, no issue regarding physician fees was ever raised in this case. The dispute centers on the issue of inappropriate care not whether or not charges were made for telephonically prescribing the Demerol.
2. Emergency Room Fees Discounted. The sponsor also indicated that the local emergency room had discounted its usual ER fee because of the appealing party's frequent visits and chronic condition, and implying that therefore there should be no question concerning use of the emergency room. The Hearing File of Record indicates that only a minimal amount of service was rendered in the emergency room and that the patient's condition did not mandate any care other than the administration of the Demerol injections--therefore "reduced charge" is somewhat of a misnomer. However, again the cost of the emergency room visits is not at issue, although use

of the emergency room as a substitute physician's office was inappropriate. Again, the primary issue is one of appropriate care--not the amount of the emergency room charge.

3. Similar Prior Claims Paid: Change in Fiscal Intermediary. According to the sponsor prior claims for similar services were paid by CHAMPUS without question. He further claimed that the appealing party had received similar services in both Uniformed Services facilities and civilian hospitals and that no question had ever been raised until in 1977 when there was a change in the CHAMPUS Fiscal Intermediary for his state of residence. It was his position that the current fiscal intermediary had denied the Demerol injections in an effort to cut costs. Although not verifiable in the Hearing File of Record, it is acknowledged that it is entirely possible that prior claims for Demerol injections may have been paid by CHAMPUS. However, without additional records, it is not possible to ascertain whether such claims also reflected similar circumstances--i.e., frequency, use of hospital emergency room, patient refusing other medications, etc. In any event the question is moot. If prior claims were paid and they did, in fact, represent similar circumstances as those in dispute, they were paid in error. And rather than indicating inappropriate claims adjudication on the part of the current CHAMPUS Fiscal Intermediary or that denial was the result of any special cost saving effort, it points to careless and ineffective claims processing on the part of the prior Fiscal Intermediary. While no effort will be made to investigate any prior claims for possible recoupment action, the current Fiscal Intermediary will be directed to carefully review future claims to assure that erroneous claims payments are not made in the future. (It is also noted that since the Fiscal Intermediary has no financial interest in the amount of CHAMPUS benefits paid out, this is entirely underwritten by the Government, no cost saving interest is involved.)
4. Principle of Estoppel Should Apply. It was further implied by the sponsor that because prior claims for Demerol injections had been paid by CHAMPUS, the Program had the obligation to continue to extend benefits whether or not the disputed services are appropriate--i.e., implying that the principle of Estoppel should apply. In effect the sponsor claimed that because benefits had been extended for similar services in the past, he and the appealing party had assumed

the Demerol injections would continue to be covered without question. As stated previously, that prior claims for similar services were paid cannot be verified. However, the issue is moot since CHAMPUS is a Federal Program and the principle of estoppel does not apply to actions of the Federal Government. Even if estoppel did apply--the kind of services in dispute in this case are those for which it may be correct to extend benefits initially or where a potential abuse situation cannot be identified immediately. Therefore, it is very likely and proper that benefits could first be extended then subsequently questioned and denied.

5. Period of Time in Appeal. The appealing party and her sponsor noted that an extended period of time had elapsed between the initial denial and the concluding stages of the appeal process. This is a legitimate complaint and one the Department of Defense is aware of and efforts are being made to improve the situation. However, it must be recognized that the formal CHAMPUS Administrative Appeals system is relatively new and only recently became operational at all levels. Procedures and staffing requirements are still in the developmental stages. It is also noted that had there been no formal appeal system available, the appealing party would not have been afforded an opportunity to present her views at a hearing or to have an appellate review by the Office of the Assistant Secretary of Defense (Health Affairs). While the delays currently in the system are acknowledged, this does not indicate a decision favorable to the appealing party should therefore be issued. Any appeal decision must be based on the specific facts in the case, in keeping with law and applicable regulations.
6. Challenge to Peer Review: Second Guessing. The attending physician opposed the use of peer review, claiming that it constituted "second guessing" the physician who was directly involved in the case. Such a reaction is not unusual when a third party raises questions concerning treatment practices. The opinion of the attending physician (as this case illustrates) is always considered in any case review but it is not necessarily controlling. It is further pointed out that the general medical community accepts peer review as the most adequate means of providing information and advice to third party payors concerning medical matters which may be in question. In this particular case all the reviewing physicians found the long term use of injections of Demerol for

migraine to be inappropriate and not in keeping with general professional standards of practice in the United States. The attending physician submitted no evidence that his treatment regimen was supported or endorsed even by his associates or other practitioners in his local community. As a matter of fact, the pattern that emerges from anecdotal information contained in the Hearing File of Record indicates that those other providers who were involved in the case expressed concern about the continued use of Demerol injections and recommended alternative therapeutic treatment regimens--in effect supporting the peer review findings.

7. Burden of Proof. It was the CHAMPUS position that the administration of Demerol injections for relief of migraine headache in the hospital emergency room constituted inappropriate care--i.e., care not in accordance with accepted medical standards in the United States. CHAMPUS further maintained that the continued use of Demerol constituted a potential drug abuse situation. The appealing party, sponsor and attending physician disagreed with these findings but submitted no evidence that substantiated their claims that the services were essential and appropriate and that the potential for drug dependency did not exist. Much of the evidence made available by the appealing party, particularly the statements of the consulting neurologist and the clinical psychologist actually supported the CHAMPUS position. Since the appealing party had ample opportunity to gather evidence that would contradict the CHAMPUS findings, it can be assumed that no other evidence was available and that the CHAMPUS conclusions were correct. The regulation requires that, "The burden of producing evidence as to a particular fact is on the party to the hearing against whom a finding on that fact would be required in the absence of further evidence." The Hearing Officer erred in his conclusion that CHAMPUS failed to support its position. The weight of evidence of professional opinion clearly indicated that the Demerol injections were found to be inappropriate for the migraine condition. Conversely, it was the appealing party and her attending physicians who were unable to present support for their positions other than their personal statements. (Reference: CHAMPUS Regulation DoD 6010.8-R Section F, Paragraph 16. i.).

RELATED ISSUE

Subsequent Claims for Similar Services. In concluding that the long term use of Demerol injections for migraine headache represents inappropriate medical care--i.e., care not provided in accordance with accepted standards of medical practice in the United States--CHAMPUS also establishes a position for any subsequent claims for this appealing party for similar services under similar circumstances. Careful examination of all claims which may be subsequently submitted to CHAMPUS by the appealing party will be required in order to ascertain that the conditions, services and circumstances are not similar to those represented by this appeal case. It is not the intention of the CHAMPUS program to deny benefits for proper use of emergency room facilities when the patient's condition requires that level of care or to preclude benefit payments for medications, if the medical information available indicates that it is being appropriately prescribed and administered. However, the Program cannot support care it determines to be inappropriate or where the circumstances indicate a strong potential for abuse.

SUMMARY

This FINAL DECISION does not imply that the appealing party did not experience migraine headaches. It only confirms the Program's position (1) that the long term use of Demerol injections in connection with migraine headache represents inappropriate care--i.e., care not provided in accordance with accepted professional standards in the United States; and (2) that continued use of Demerol in this case establishes a strong potential for drug abuse.

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Out review indicates the appealing party has been afforded full due process in her appeal. Issuance of this FINAL DECISION is the concluding step in the CHAMPUS the appeals process. No further administrative appeal is available.



Vernon McKenzie
Principal Deputy Assistant Secretary of
Defense (Health Affairs)