ASSISTANT SECRETARY OF DEFENSE
WASHINGTON, D. C. 20301

HEALTH AFFAIRS

BEFORE THE OFFICE, ASSISTANT

SECRETARY OF DEFENSE (HEALTH AFFAIRS)

7 JUN 1984

UNITED STATES DEPARTMENT OF DEFENSE

Appeal of	)	
	)	
Sponsor:	)	OASD(HA) No. 84-05
	)	FINAL DECISION
SSN:	)	

This is the FINAL DECISION of the Assistant Secretary of Defense (Health Affairs) in the CHAMPUS appeal OASD(HA) Case File 84-05 pursuant to 10 U.S.C. 1071-1089 and DoD 6010.8-R, chapter X. The appealing party in this case is the spouse of a retired officer in the United States Air Force. The sponsor has been appointed as the personal representative of the beneficiary for purposes of this appeal.

The appeal involves a question of CHAMPUS coverage of prescription drugs for the treatment of numerous medical problems including migraine cephalalgia, painful right heal and ankle, glaucoma left eye, potassium deficiency, hypertension, angina, arthritis, thrombophlebitis, and chronic rhinitis. The total charge incurred by the beneficiary for prescription drugs for the period in issue is $907.95. Numerous claims were submitted in 1981 and 1982 to the CHAMPUS Fiscal Intermediary for Arizona (at that time, Blue Shield of California) for Nubain and Phenergan injections as well as for Blocadren, Calan, and Procardia. The fiscal intermediary conducted nine informal reviews and seven reconsideration reviews. As a result of these reviews, claims for medications totaling $907.75 were denied CHAMPUS cost-sharing. The fiscal intermediary's denials were based upon the rationale that the medical necessity and continuous use of these drugs had not been documented.

The hearing file of record, the tapes of 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 $907.95. It is the Hearing Officer's recommendation that CHAMPUS coverage for the prescription drugs, namely Nubain and Phenergan, be denied because these injections were neither medically necessary nor appropriate medical care. It is also the recommendation of the Hearing Officer that CHAMPUS, as agreed to prior to the hearing, cost-share the claims for the prescription drugs Blocadren,

Calan, and Procardia. The Director, OCHAMPUS, concurs in the recommendations of the Hearing Officer and recommends adoption of the Recommended Decision as the FINAL DECISION.

The Assistant Secretary of Defense (Health Affairs), after due consideration of the appeal record, concurs in the recommendation of the Hearing Officer to deny CHAMPUS payment for the prescription drugs Nubain and Phenergan and concurs in the recommendation of the Hearing Officer to allow CHAMPUS cost-sharing of the prescription drugs Blocadren, Calan, and Procardia. The Assistant Secretary of Defense (Health Affairs) hereby adopts the recommendation of the Hearing Officer as the FINAL DECISION.

The FINAL DECISION of the Assistant Secretary of Defense (Health Affairs) is, therefore, to approve CHAMPUS cost-sharing of the prescription drug Blocadren, Calan, and Procardia and to deny CHAMPUS cost-sharing of the prescription drugs Nubain and Phenergan. The decision to deny cost-sharing of Nubain and Phenergan is based on findings that these prescription drugs were not medically necessary nor appropriate medical care in the treatment of the beneficiary's diagnosed illness and not in keeping with the generally accepted norm for medical practice in the United States.

FACTUAL BACKGROUND

On January 6, 1982, the 60-year-old beneficiary suffered from severe chest pains, chills, numbness of arms and hands, and a loss of ability to breathe without pain. The sponsor took the beneficiary to the emergency room at Desert Samaritan Hospital where the beneficiary was treated for cardiac arrest. Approximately 2 hours later the beneficiary was admitted to the intensive care unit of the hospital and placed under the care of a cardiologist. The beneficiary remained in the intensive care unit for 3 days. Subsequently, it was determined that she had not suffered a heart attack and that the severe pains were the result of angina with some arterial blockage. The beneficiary was moved from the intensive care unit to the intermediate care unit where she was monitored for the next few days. During her stay in the intermediate care unit, the cardiologist determined that the beneficiary required a catheterization procedure (angiogram) in which it was disclosed that the beneficiary did have blockage in several minor arteries which caused the chest pains. The beneficiary was released from the hospital on January 13, 1982.

The beneficiary continued to experience the attacks of angina pain for which she was prescribed nitroglycerin tablets. Although this medication controlled the chest pain, it caused severe migraine headaches. The beneficiary's physician controlled these headaches by injections of Nubain and Phenergan, prescribing these drugs with the concurrence of the beneficiary's cardiologist.

During the beneficiary's treatment for angina, a new drug treatment (Procardia) was approved by the Food and Drug Administration and was prescribed by the beneficiary's physician with the concurrence of the cardiologist. Although this new drug seemed to control the angina pain to a degree, it did not completely stop the attacks. When the attacks occurred, the beneficiary used nitroglycerin tablets which resulted in severe headaches. The headaches then were relieved by injections of Nubain and Phenergan.

The treating physician, Dr. Roger S. Anderson, described the beneficiary's medical condition as follows:

> "I have been treating [the beneficiary] as a patient since March 1980. In the ensuing months since that time, she has suffered from many medical problems, currently still suffering from medical problems which require continual treatment. I would like to give just a brief history of some of these problems. First problem, [the beneficiary] suffers from Migraine Cephalgia. It is classical migraine in origin on one side of the head only, it is unrelated to diet; it [is] also unresponsive to Ergot preparations or to Darcovett. [The beneficiary] is allergic to both Codeine and Morphine as well as Valium. The only two medications that can bring relief of these Migraines are Nubain, which is a non-narcotic injection which is not available in pill form, and injectible or oral Demoral. I have given [the beneficiary] both injectible and oral Demeral very rarely because she possesses a great fear of taking any kind of narcotics or tranquilizers.
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> "She also suffers extensive pain in both her right heel and ankle and with both knees. She has been seen in consultation by an Orthopedic surgeon for this condition as well as a Podiatrist and during a good portion of the year in 1981, in fact she was wearing both casts and supports. Xray evidence reveals that she has extensive calcifications on the Achilles tendon and this produces pain with walking.
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> "[The beneficiary] has been hospitalized in the past twelve months for the removal of a cataraxt [sic]. It should be noted she also suffers from Glaucoma of the left eye.
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> "She also has been hospitalized in the past twelve months for heart irregularity. She is

> currently taking Blockadrin b.i.d. She is also taking Procardia. Procardia was instituted as soon as it became available. Nitroglycerin products give her severe Cephalgia, where also no relief from the pain. [sic] Cardiac catherization [sic] of the heart did reveal a heart disease; she is currently being followed for this condition.
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> "Also currently treating [the beneficiary] for arthritis; there have been two relapses in six months. Also she has been treated in the last six months for Thrombophlebitis of each leg. She suffers from chronic Rhinitis and is on medication for this intermittently throughout the year.
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> "All the above things point out that this lady does have severe medical problems which require ongoing medical therapy and continual consultation."

During the period for which the beneficiary was being treated by Dr. Anderson and receiving the injections of Nubain and Phenergan, the beneficiary would submit CHAMPUS claims for these injections. The CHAMPUS Fiscal Intermediary for Arizona cost-shared the injections in the amount of $4.00 per injection. The actual cost of the injections ranged from $10.00 to $25.00. Because the fiscal intermediary did not cost-share a higher amount, the sponsor requested the fiscal intermediary to review the disallowance for the injections. On April 26, 1982, the fiscal intermediary informed the beneficiary that if she desired to have these claims reviewed that further documentation from her attending physician was necessary and that the doctor should address the medical necessity for continuous prescription of the drugs claimed. The fiscal intermediary treated the beneficiary's inquiry as an informal review consideration.

On May 4, 1982, the attending physician responded as follows for the reconsideration review:

> "This letter, on behalf of my patient, [the beneficiary], is written as you requested in your letter to [the beneficiary] of 4-26-82, as it relates to the medications I have prescribed for her on a continuous basis since approximately two years ago.
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> "For various conditions, as listed below, she is taking the following prescription drugs which I have both authorized and requested she take to alleviate various conditions with which she is afflicted.

"1. For night time cramps in her leg, due to a pattellectomy in 1967, I have prescribed the drug Norflex to be taken on an as required basis to assist in relieving the cramps. Refills are authorized as required.

"2. For intermittent headache pains, I have prescribed Fiorinal to be used to relieve migraine headache attacks, if possible. When she does require a refill of this medication, the druggist calls me and I authorize it.

"3. Slow-K has been prescribed, with refills when required, for a potassium deficiency associated with the taking of other drugs, listed below, for the hypertension from which she suffers.

"4. Dalmane, to assist her in sleeping, is prescribed for use when required. If a refill is required, the pharmacy checks with me for authorization for the refill.

"5. Lasix, a dieuretic, is used in the control of hypertension and is prescribed for daily use. Refills are authorized when required.

"6. Inderal, for control of hypertension, was used for approximately six months; however, after her angina seizure and subsequent hospitalization in January of 1982, this drug was replaced by other, newer medications.

"7. The drug, Procardia, one of those in question on this claim, is used in the control of angina and was only recently authorized for use by the FDA. It was prescribed for [the beneficiary] as soon as it became available; however, the success of its action for her was not of the highest degree so it was discontinued after use for approximately two months. I did, however, authorize this drug for her as soon as it was available.

"8. A second new drug, Calan, was approved by the FDA for general use in the treatment of Angina approximately one month ago. [The beneficiary] was started on this newer drug; and, to date, has had some good success with it, although the more effective dosage is still to be determined. While it seems to be working to a degree, it is too soon to come

to a definite conclusion as to its total effect on control of the angina condition existing in [the beneficiary].

"9. Blocadrin [sic], another recent addition to the pharmacoepia, is also used to assist in the control of angina. [The beneficiary] is taking this, at present, along with the Calan.

"10. Nitrobid, used in the relief of angina pain, was prescribed and is used when the pain starts; however, the success rate has not been too high in relieving the severe attacks experienced.

"11. Nitroglycerine tablets have also been prescribed and are the only drug that can actually relieve the severe angina attacks suffered by [the beneficiary]; however, the use of the nitroglycerine tablets has far reaching side-effects which result in a severe migraine headache to the patient. These headaches, similar to the classic migraine headaches, defy relief by any form of oral medication with the result that an injection is required to calm the headache to a tolerable degree.

"In my opinion, it is medically necessary that [the beneficiary] continue to use the drugs in the prescribed dosage at the prescribed time if her overall condition is to improve.

"I understand, too, from [the beneficiary] that there is some question on your part as to the medical necessity of her receiving the injections I have prescribed for her on a recurring basis in order to alleviate the pain and suffering she has endured for many years from the migraine headaches.

"Her migraine attacks are the classical type of migraine with the flashing lights, nausea, vomiting, etc., that are so common to those who suffer from this affliction. Her medical history indicates that she has suffered from severe migraine headaches for over thirty years. They are, apparently, brought on by nervousness, stress, and anxiety, as she is a highly emotional person. I treat her for the migraine attacks (after she has taken the prescribed oral medication with no relief)

> with an injection of 10 mg Nubain and 75 mg Phenergan.
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> "Since her hospitalization in January 1982, whenever she has an angina attack, the pain from that attack can be controlled, and is, by the use of the nitroglycerine tablet. However, the use of the nitro tablet triggers a migraine-type headache that can only be completely alleviated by using the same type of injection with which I have treated her in the past; namely, an IM injection of 10 mg Nubain and 75 mg Phenergan.
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> "[The beneficiary] has a deep seated fear of using Demerol, because it is a narcotic; she is allergic to Morphine, Codeine, Novacaine and Valium; and, oral medications for the severe headache pain are completely ineffective. Therefore, it is a medically sound practice to use, as often as I see the necessity for it, the injections which have been and will be prescribed by me. . . ."

Because of the denial of cost-sharing of the numerous claims submitted to the fiscal intermediary, the sponsor, acting as the personal representative of the beneficiary, submitted a written request to OCHAMPUS for review of the denials. In preparation for the issuance of the Formal Review Decision, the case file was submitted to the Colorado Foundation for Medical Care for medical review. This medical review was conducted by two physicians, one with a specialty in occupational medicine and the other with a specialty in internal medicine. These reviewing physicians were asked to render an opinion as to whether the use of Nubain, Phenergan, Blocadren, and Procardia was medically necessary in the treatment of the beneficiary's condition.

These physicians opined that the treating physician's statement that Nubain was a non-narcotic was wrong. They stated that Nubain is a narcotic and that prolonged and frequent use of the drug can bring on nausea and vomiting which may be withdrawal symptoms associated with the use of Nubain. It was their opinion that the diagnosis of migraine headaches was incorrect because migraine headaches usually do not follow the pattern indicated by the beneficiary's visits to the physician for the injections. These reviewing physicians questioned the diagnosis of migraine headache and also questioned the medical necessity of the injections received. It was their opinion that the narcotics and sedatives were given as a maintenance program, not because they were medically necessary for what the reviewer's considered a questionable diagnosis by the treating physician.

The reviewing physicians were also asked to furnish opinions concerning the appropriateness of the use of the Nubain, Phenergan, Bolcadren, and Procardia. In their opinions, the prescription of these drugs for the beneficiary's medical condition was not appropriate treatment. They opined that these drugs were not solving the beneficiary's problems and that the injections may be contributing to her problems by inducing withdrawal symptoms. Finally, these reviewing physicians indicated that a report from the cardiologist would be helpful in evaluating the appropriateness of these medications to control the angina. The Medical Director, OCHAMPUS, after review of the case file, concurred in the findings of the reviewing physicians.

Based on the information provided by the medical reviewers, the OCHAMPUS Formal Review Decision found that the use of Phenergan and Nubain for migraine headaches was not medically necessary because a diagnosis of migraine headaches was not established and the use of these medications was not appropriate medical care. In addition, it was concluded that these medications were not solving the patient's problems and could be causing withdrawal symptoms. This review decision also found that the diagnosis of angina was not established and, thus, the medications to control angina pain including Procardia, Blocadren, and Calan could not be considered medically necessary treatment for the beneficiary. Therefore, the OCHAMPUS Formal Review Decision found that erroneous payments had been made for the use of Phenergan and Nubain from March 1980 through June 5, 1982, and that recoupment action should be initiated.

In response to this decision, the beneficiary's representative requested a hearing. In connection with that request, the representatives provided the following additional information from the treating physician:

> "[The beneficiary] suffers from several conditions that require current and ongoing treatment in the office, in the hospital, and occasionally in the emergency rooms. She suffers from coronary artery disease with severe and many times, unresponsive angina. In an effort to bring this condition under control both Procardia, Calan, Blocadren, and Inderol have been used as well as many forms of nitroglycerine, both sublingual, and time released. At the present time [the beneficiary] has started back on Procardia. She suffered extreme constipation while on Calan. She is currently taking 20 mg. of Procardia tid. Sublingual nitroglycerine will help with some of the angina attacks however, it is a proven fact with all nitroglycerine that severe cephalgia can result. She has been seen on numerous occasions after taking the sublingual nitroglycerine that required the use of IM

medications for the cephalgia and to relieve chest pain. All medications to relieve angina have been tried on [the beneficiary] with varying amount of success, however, because her condition has never stabilized, she still requires frequent treatment in the office.

"[The beneficiary] suffers from classical migraine cephalgia. In the past both narcotic medication and non-narcotic medications have been tried. She is allergic to Codeine, morphine, as well as Valium. While these could be used perhaps to alleviate some of the migraines cephalgia, due to her allergies this is not possible. At the present time Demerol orally is used occasionally. Demerol injectable is used, but in an effort to keep the patient away from narcotic medication that can become habit forming. I am currently using Nubain. When Nubain becomes available in oral form she will be switched to this form of medication.

"In the past twelve months [the beneficiary] has been seen on several occasions with continuing problems with her leg and knee. She has had both patellas removed, she has long standing problems with her ankles and feet. She has been seen in consultation by both orthopedic surgeons and podiatrists. At this time no further surgery can be done. I am treating these conditions with anti-inflammatory drugs such as Feldene. She has also been on Clinoril for this, however Clinoril does cause her stomach distress. She also was seen in the office for severely sprained ankle and she has since recovered from that.

"Because of the above mentioned medical conditions I request that you reconsider reimbursement for [the beneficiary] for these ongoing medical conditions. I can assure that [the beneficiary] does not receive any injections for pain unless she is either suffering from angina or classical migraine cephalgia, or cephalgia secondary to taking nitroglycerine for which other medications have not been proven to be effective.

On April 18, 1983, the treating physician provided an update of the beneficiary's medical condition. In his letter, Dr. Anderson commented as follows:

"[The beneficiary] has asked me to update previous correspondence to your office regarding the medical necessity of the medications and emergency room visits for the time periods of November 3, 1982 thru November 8, 1982, January 3, 1983 thru January 7, 1983, and January 16, 1983.

"I had seen [the beneficiary] in the office on November 3, 1982. Williams AFB Hospital had advised the patient to have an EKG taken, although they apparently did not want to take it. She had had some emotional trauma that day and had an anginal attack. At the time I saw her, her heart rate and rhythm was regular. The EKG did show signs of ST segment depression. A diagnosis of acute anginal attack was made; and, apparently, the attack returned sometime after my office had closed. I also saw [the beneficiary] on November 4, 1982. At that time she had rales and rhonci in her chest and a diagnosis of bronchitis was made. She was started on medication; no injection was given at that office visit. I saw her again on November 8, 1982, and a chest x-ray was taken in my office at that time revealed pneumonitis [sic]. She was placed on different antibiotics and no injectable medication was given other than an antibiotic at that time.

"On December 23, 1982, [the beneficiary] fell down with virtually all her weight going on her left knee. This caused severe hematoma of the left knee. The temperature of the knee was approximately 2-3 degrees warmer than the rest of the leg. Much echymosis was noted as well as fluid.

I saw [the beneficiary] several times over the next 2 to 2½ weeks, for her problems with her knee. And this apparently covers the time between January 3, 1983, and January 7, 1983, in which she went to the hospital after my office was closed.

"I had not seen [the beneficiary] on January 16, 1983; however, I did see her on the 15th of January, at which time she was still complaining of her leg, and also admitted stomach tenderness, chest pain, nausea, and vomiting. At that time in my office she was given sublingual levisin in an effort to stop what I diagnosed as pylorospasm.

"At the present time, [the beneficiary] suffers from the following conditions:

1. Angina pectoris, which responds to sublingual nitroglycerin; however, sublingual nitroglycerin produces severe cephalgia in [the beneficiary].
2. Cephalgia (the classical type).
3. Arthritis of each knee.
4. She also suffers from some anxiety and depression.

"These are continuing medical problems which require continuing, ongoing medical care.

"To treat these ongoing problems, [the beneficiary] is currently taking, orally, on a regular basis, Procardia, Blocadren and Persantine in an attempt to control the angina. She is also taking, orally, Slow K and Zaroxylyn.

"All of these medications I consider necessary on a continuing basis to attempt to alleviate the conditions outlined.

"There are times when the medications taken orally are not sufficient to control the attacks of angina with any great degree of success. When angina pains do occur, I have instructed [the beneficiary] to take the sublingual nitroglycerin tablets which result in the alleviation of the chest pain. However, the use of these nitroglycerin tablets produces the severe cephalgia as I have outlined above.

"In order to control this cephalgia, I use an IM injection of a combination of Nubain and Phenergan which does produce the pain relieving results required and desired. These injections are given only when necessary for the relief of the cephalgia caused by the nitroglycerin tablets.

"It is my understanding that Nubain will be released in December of this year in an oral form, at which time I will put [the beneficiary] on the oral Nubain to relieve the cephalgia resulting from the nitroglycerin tablets.

"However, until the oral Nubain is available, it will be necessary to continue to use the injection shown above on a continuing basis,

> as required, in order to provide the relief necessary.
>
> "Again, [the beneficiary] has continuing problems that require continuous, ongoing medical treatment. The program I have her on at this time appears to be working and will be continued.

The beneficiary also provided the hospital notes for the January hospitalization for angina which indicate that the discharge diagnosis was angina, atherosclerotic vascular disease, migraine headaches, status post right lens implant, history of osteoarthritis, history of positive TB skin test, status post patellectomy, history of angle glaucoma, and status post bilateral iridectomy.

Because of the additional information, the case file was once again submitted to the Colorado Foundation for Medical Care for medical review. The review was conducted by the same two physicians who performed the previous review. In this second medical review, the physicians were asked whether the use of Nubain, Phenergan, Blocadren, and Procardia were medically necessary for the treatment of the beneficiary. In response to this question, it was the opinion of the two reviewing physicians that the use of Blocadren and Procardia in the management of angina was medically necessary treatment; however, it was also their opinion that the use of injections of Nubain and Phenergan to treat nitroglycerin-induced headaches was not medically necessary treatment nor in keeping with the generally accepted norm for medical practice in the United States. It was their opinion that, rather than giving the patient narcotic injections for nitroglycerin-induced headaches, the physician should have stopped or reduced the amount of nitroglycerin or changed to another vasodilator because the headaches were a sign of nitroglycerin overdosage.

Based on this medical review, the issue of the medical necessity of Procardia, Blocadren, and Calan was not in dispute at the hearing.

A hearing was held by Sherman Bendalin, Hearing Officer, on November 9, 1983. The Hearing Officer has submitted his Recommended Decision and all prior levels of administrative reviews have been exhausted. Issuance of a FINAL DECISION is proper.

ISSUES AND FINDINGS OF FACTS

The primary issues in this appeal are (1) whether the prescription drugs (Nubain and Phenergan injections) provided the beneficiary for the treatment of migraine headaches were medically necessary and in keeping with the generally accepted norm for medical practice in the United States, and (2) whether a drug abuse situation existed resulting in the erroneous payment

of CHAMPUS claims for prescription drugs related to the drug abuse.

Medical Necessity/Appropriate Level of Care

Under the CHAMPUS Regulation, DoD 6010.8-R, chapter IV, A.1., the CHAMPUS Basic Program will cost-share medically necessary services and supplies required in the diagnosis and treatment of illness or injury, subject to all applicable limitations and exclusions. Services which are not medically necessary are specifically excluded (chapter IV, G.1.). Under chapter II, B.104., medically necessary is defined as:

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

Appropriate medical care is defined in chapter II, B.14., as follows:

> "14. Appropriate Medical Care. 'Appropriate medical care' means:
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> "a. That medical care where the medical services performed in the treatment of a disease or injury, or in connection with an obstetrical case, are in keeping with the generally acceptable norm for medical practice in the United States;
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> "b. The authorized individual professional provider rendering the medical care is qualified to perform such medical services by reason of his or her training and education and is licensed and/or certified by the state where the service is rendered or appropriate national organization or otherwise meets CHAMPUS standards; and
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> "c. The medical environment in which the medical services are performed is at the level adequate to provide the required medical care."

The criteria for CHAMPUS coverage of prescription drugs and medicines are set forth in DoD 6010.8-R, chapter IV, D.3.f., in part, as follows:

> "f. Prescription Drugs and Medicines. Prescription drugs and medicines which by law of the United States require a physician's or dentist's prescription and which are ordered

> or prescribed for by a physician or dentist (except that insulin is covered for a known diabetic, even though a prescription may not be required for its purchase) in connection with an otherwise covered condition or treatment, including Rhogam.
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> "(1) Drugs administered by a physician or other authorized individual professional provider as an integral part of a procedure covered under Sections B or C of this CHAPTER IV (such as chemotherapy) are not covered under this subparagraph inasmuch as the benefit for the institutional services or the professional services in connection with the procedure itself also includes the drug used.
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> "(2) CHAMPUS benefits may not be extended for drugs not approved by the Food and Drug Administration for general use by humans (even though approved for testing with humans.)"

CHAMPUS claims are subject to review for quality of care and appropriate utilization. (See paragraph A.10., chapter IV, DoD 6010.8-R.) Prescription drug claims are also subject to postpayment utilization review and claims that fail established postpayment utilization review screens or appear to involve abnormal patterns of prescribing are developed through associated claims history or the request for additional medical records. This review process is always retrospective because each claim is reviewed after the fact of the purchase of the medical supply or service involved. Implicit in this utilization review process is the possibility that a particular medication supply or service at any time may be determined to be not medically necessary or beyond an appropriate level. This also means that even though benefits are initially extended on a particular claim, postpayment review may result in the emergence of an aberrant pattern which calls into question the medical necessity or appropriate level of the services or supplies involved.

To constitute a CHAMPUS covered service, the prescription of Nubain and Phenergan must, therefore, be adequate for the diagnosis and treatment of the beneficiary's illness and, correspondingly, treat her disease or illness. The illness or disease attributed to the beneficiary herein is migraine headaches resulting from the prescription of nitroglycerin for the treatment of the beneficiary's angina. The acceptance and efficacy of the use of Nubain and Phenergan in treatment of the migraine headaches resulting from nitroglycerin treatments for angina must, therefore, be documented.

The appeal file herein contains several medical review opinions both from the fiscal intermediary and physicians associated with the Colorado Foundation for Medical Care. In the opinions of the

reviewing physicians, these two drugs were not medically necessary for the treatment of the beneficiary's condition. Further, it was opined that the continuing use of these medications for any period of time was not in keeping with the generally accepted norm for medical practice in the United States. Based on these professional opinions and other evidence in the record, the Hearing Officer arrived at the same conclusion.

I concur with the findings of the Hearing Officer to the effect that these drugs are not medically necessary nor appropriate for the treatment of the beneficiary's medical condition. After careful review of the record, I conclude that the hearing record supports the Hearing Officer's findings and that the use of these two prescription drugs was not medically necessary and not within the acceptable norm for practice in the United States.

Based on my review of the file, the testimony provided at the hearing, the Hearing Officer's Recommended Decision, and the medical reviews conducted by the Colorado Foundation for Medical Care and by the fiscal intermediaries, I find that the use of Nubain and Phenergan for treatment of this beneficiary's condition was not medically necessary nor appropriate and that it was not in keeping with the generally accepted norm for medical practice in the United States. The record does not establish the medical necessity nor appropriateness of these prescription drugs during the course of use by the beneficiary as supported by documented diagnoses or definitive symptoms.

Drug Abuse

CHAMPUS does not cost-share prescription drugs related to an existing or potential drug abuse situation. The exclusion from CHAMPUS coverage is set forth in DoD 6010.8-R, chapter IV, E.11., as follows:

> "11. Drug Abuse. Under the CHAMPUS Basic Program, benefits may be extended for medically necessary prescription drugs required in the treatment of an illness or injury or in connection with maternity care (refer to Section D. of this CHAPTER IV). However, CHAMPUS benefits cannot be authorized to support and/or maintain an existing or potential drug abuse situation, whether or not the drugs (under other circumstances) are eligible for benefit consideration and whether or not obtained by legal means.
>
> "a. Limitation on Who Can Prescribe Drugs. CHAMPUS benefits are not available for any drugs prescribed by a member of the beneficiary/patient's family or by a non-family member residing in the same

household with the beneficiary/patient (or sponsor). CHAMPUS Contractors are not authorized to make any exception to this restriction.

"b. Drug Maintenance Programs Excluded. Drug maintenance programs where one addictive drug is substituted for another on a maintenance basis (such as methadone substituted for heroin) are not covered. Further, this exclusion applies even in areas outside the United States where addictive drugs are legally dispensed by physicians on a maintenance dosage level.

"c. Kinds of Prescription Drugs Which Are Carefully Monitored by CHAMPUS for Possible Abuse Situations.

"(1) Narcotics. Examples are morphine and demerol.

"(2) Non-Narcotic Analgesics. Examples are Talwin and Darvon.

"(3) Tranquilizers. Examples are Valium, Librium, and Meprobamate.

"(4) Barbiturates. Examples are Seconal and Nembutal.

"(5) Non-barbiturate Hypnotics. Examples are Doriden and Chloral Hydrate.

"(6) Stimulants. Examples are Amphetamines and Methedrine.

"d. CHAMPUS Contractor Responsibilities. CHAMPUS Contractors are responsible for implementing utilization control and quality assurance procedures designed to identify possible drug abuse situations. The CHAMPUS Contractor is directed to screen all drug claims for potential over-utilization and/or irrational prescribing of drugs, and to subject any such cases to extensive review to establish the necessity for the drugs and their appropriateness on the basis of diagnosis and/or definitive symptoms.

"(1) When a possible drug abuse situation is identified, all claims for drugs for that specific beneficiary and/or provider will be suspended pending the results of a review.

"(2) If the review determines that a drug abuse situation does in fact exist, all drug claims held in suspense will be denied.

"(3) If the record indicates previously paid drug benefits, the prior claims for that beneficiary and/or provider will be reopened and the circumstances involved reviewed to determine whether or not a drug abuse situation also existed at the time the earlier claims were adjudicated. If drug abuse is subsequently ascertained, benefit payments previously made will be considered to have been extended in error and the amounts so paid recouped.

"(4) Inpatient stays primarily for the purpose of obtaining drugs and any other services and supplies related to drug abuse situations are also excluded.

"e. Unethical or Illegal Provider Practices Related to Drugs. Any such investigation into a possible drug abuse situation which uncovers unethical or illegal drug dispensing practices on the part of an institution or physician, will be referred to the professional and/or investigative agency having jurisdiction. CHAMPUS Contractors are directed to withhold payment of all CHAMPUS claims for services and/or supplies rendered by a provider under active investigation for possible unethical or illegal drug dispensing activities.

"f. Detoxification. The above monitoring and control drug abuse situations shall in no way be construed to deny otherwise covered medical services and supplies related to drug detoxification (including newborn addicted infants) when medical supervision is required."

The Hearing Officer found that the record indicated the beneficiary was not a drug addict nor a drug abuser; however, it did appear that a drug overutilization situation existed during the period in question and, therefore, a drug abuse situation, as defined in the Regulation, precluded cost-sharing by OCHAMPUS of the multiple claims for the prescriptions of Nubain and Phenergan. I find the hearing record supports the findings of the Hearing Officer.

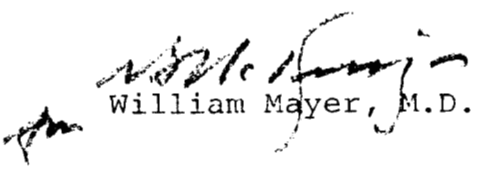
The Department of Defense recognizes that the beneficiary was following the orders of her physician. While the physician may endorse programs he believes may assist individual patients, I am

constrained by law and regulation to authorize benefits only for services and supplies which are determined to be medically necessary and generally accepted in the treatment of disease or illness. In addition, CHAMPUS coverage of otherwise authorized prescription drugs is prohibited in actual or potential drug abuse situations unless the medical record establishes the necessity for the drugs and the appropriateness of the drugs on the basis of documented diagnosis or definitive symptoms.

Based on the record in this case, I concur with the Hearing Officer's finding that the beneficiary was in a potential drug abuse situation during the period of time that she was prescribed Nubain and Phenergan. I further find that the medical record fails to establish the necessity and appropriateness of the prescribed drugs on the basis of the beneficiary's diagnoses or definitive symptoms during the period for which she was receiving these drugs. Therefore, CHAMPUS cost-sharing of claims for Nubain and Phenergan must be denied.

SUMMARY

In summary, it is the FINAL DECISION of the Assistant Secretary of Defense (Health Affairs) that the prescription drugs (Nubain and Phenergan injections) claimed by the beneficiary were not medically necessary and were not appropriate care. The use of these drugs in the treatment of the beneficiary's diagnosed condition or definitive symptoms was not in keeping with the generally accepted norm for medical practice in the United States. Therefore, the use of these drugs is not covered under CHAMPUS and the appeal of the beneficiary for the CHAMPUS cost-sharing of these drugs is denied. Because it has been determined that CHAMPUS has erroneously paid for some of the injections of these prescription drugs, the Director, OCHAMPUS, is directed to review this issue and initiate recoupment action as appropriate under the Federal Claims Collection Act. Issuance of this FINAL DECISION completes the administrative appeals process under DoD 6010.8-R, chapter IX and no further administrative appeal is available.



William Mayer, M.D.