

HYPERBARIC MEDICINE

TODAY

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COVERAGE ISSUES - MEDICAL PROCEDURES

14. Actinomycosis, only as an adjunct to conventional therapy when the disease process is refractory to medical and surgical treatment, (ICD-9-CM diagnosis 039.0-039.4, 039.8, 039.9).
15. Actinomycosis of the lower extremities in patients who meet the following three:
- a. Patient has type I or type II diabetes and has a lower extremity wound that is due to diabetes;
 - b. Patient has a wound classified as Wagner grade III or higher; and
 - c. Patient has failed an adequate course of standard wound therapy.

The use of HBO therapy is covered as adjunctive therapy only after there are no measurable signs of healing for at least 30 days of treatment with standard wound care in patients with diabetic wounds and must be used in addition to standard wound care. Standard wound care in patients with diabetic wounds includes: assessment of a patient's vascular status and correction of any vascular problems in the affected limb if possible; optimization of nutritional status; optimization of glucose control; debridement by any means to remove devitalized tissue; maintenance of a clean, moist bed of granulation tissue with appropriate moist dressings; appropriate off-loading; and necessary treatment to resolve any infection that might be present. Failure to respond to standard wound care occurs when there are no measurable signs of healing for at least 30 consecutive days. Wounds must be evaluated at least every 30 days during administration of HBO therapy. Continued treatment with HBO therapy is not covered if measurable signs of healing have not been demonstrated within any 30-day period of treatment.

B. Noncovered Conditions. --All other indications not specified under §35-10 (A) are not covered under the Medicare program. No program payment may be made for any conditions other than those listed in §35-10(A).

No program payment may be made for HBO in the treatment of the following conditions:

1. Cutaneous, decubitus, and stasis ulcers.
2. Chronic peripheral vascular insufficiency.
3. Anaerobic septicemia and infection other than clostridial.
4. Skin burns (thermal).
5. Senility.
6. Myocardial infarction.
7. Cardiogenic shock.
8. Sickle cell anemia.
9. Acute thermal and chemical pulmonary damage, i.e., smoke inhalation with pulmonary insufficiency.
10. Acute or chronic cerebral vascular insufficiency.
11. Acute or chronic cerebral vascular insufficiency.
12. Hepatic necrosis.
13. Aerobic causes of chronic brain syndrome (Pick's disease, Alzheimer's disease, Korsakoff's disease).
14. Tetanus.
15. Systemic aerobic infection.
16. Organ transplantation.
17. Organ storage.
18. Pulmonary emphysema.
19. Exceptional blood loss anemia.
20. Multiple Sclerosis.
21. Arthritic Diseases.
22. Acute cerebral edema.

FROSTBITE & HBOT

ACUTE & CHRONIC CARBON
MONOXIDE POISONING

GOOD BYE TO DR. EDWARD TELLER

A Huge Advocate of HBOT

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MEDICARE'S NONCOVERED CONDITIONS; A Conversation With Dr. George B. Hart by David Freels

Editor's Notes

The following article recounts a phone conversation between Dr. George Hart and David Freels in August of 2000. The phone conversation was intended to be information for David Freels' legal case and not intended to be an investigational article on sickle cell anemia or anything else. After David Freels had this amazing conversation he called me to ask if I knew anything about Dr. Hart or the "Noncovered" indications. I told Mr. Freels that I knew Dr. Hart but was not aware how involved he was with the creation of the list. I told David I was very interested in hearing Dr. Hart's story because if there was any truth to it, it would change our field and answer the age old question "what is it that is holding hyperbarics back?"

I called Dr. Hart in September of 2000 to check Mr. Freels' story. I did not tell Dr. Hart that I spoke with David but rather pursued a line of questioning about the Medicare "Noncovered" conditions. Dr. Hart confirmed every thing David Freels writes here and told me that he had been waiting 30 years for someone to ask him about the "Noncovered" indications. This article has been three years coming because Mr. Freels and I have both, slowly over time, tried to appeal to Dr. Hart to come forward with the complete details of who told him to suppress these indications or take the position he did. My first conversation ended with Dr. Hart telling me he would give me a complete account for publication (i.e.

naming names) but he first had several loose ends to tie up. I called Dr. Hart back two weeks later to discuss this again and he told me he had accepted a position back at Long Beach Memorial Hospital and had changed his mind about the article and didn't want to discuss it any further. This was so abrupt that I continued over the next few years trying to persuade him as a medical professional, as a Naval officer, and as a concerned citizen, to please come forward and correct this terrible injustice. I spent countless hours on the phone, sending E-mails, pleading with him to go public with his story.

I can affirm that through my phone conversations and E-mails that everything David Freels has reported here was also reported to me by Dr. Hart. We are publishing one of the letters Dr. Hart wrote to David to verify this conversation and its original purpose (sickle cell anemia and the other "Noncovered indications").

I have appealed to Dr. Hart on every level to please come forward with his story. He has refused, telling me "I will let my peers judge me on my accomplishments."

These are the events as relayed from David Freels in a phone conversation in August of 2000 from his notes.

My wife and I first requested Medicaid reimbursement for our son Jimmy in 1999. Jimmy suffers from mid-brain injury but like 95% of all brain-injured children, he made tremendous gains with Hyperbaric Oxygen Therapy. After three denials between May and December, 1999, we requested a hearing before an Administrative Law Judge (ALJ). Our first hearing date was July 6, 2000 and scheduled to reconvene in late September, 2000. The whole issue was about accessing off-label HBOT. A big problem was Georgia Medicaid was following Medicare policy on HBOT reimbursement. Medicare has

14 "Covered Conditions" of HBOT and 22 "Noncovered Conditions". According to the Ethics Committee report of the Undersea and Hyperbaric Medical Society (UHMS), the "Noncovered" list is equivalent to an off-label uses list.

It occurred to me that maybe Georgia Medicaid had already reimbursed HBOT for one of the other "Noncovered Conditions", which would set a precedent and open the door for us to also access off-label hyperbaric oxygen therapy.

For this article I did a Medline review of

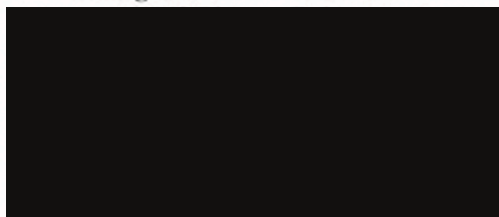
studies & references for each "Noncovered Condition AND hyperbaric". The number of references appears in parentheses. I was surprised to learn there was so much evidence on HBOT and its efficacy for nearly everything on the "Noncovered" list.

According to Section 35-10B of the Medicare Coverage Issues Manual, "No program payment may be made for HBO in the treatment of the following conditions:"



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George Babe Hart MD FACS



August 28, 2000

David Freels



Dear Mr Freels

As per tel-con the following are unreported uses of hyperbaric oxygen in the treatment of conditions arising directly from **Sickle Cell Disease**:

1. **Sickle Cell Priapism.**

This has a high morbidity and mortality. It is characterized by tumescence of the shaft of the penis. (See enclosed photographs of the one case that we have treated). The patient was treated twice daily at 2 ATA in a monoplace hyperbaric chamber and was completely relieved after two weeks of Rx. Note: The patient had been hospitalized for the condition over a nine month period – having had “hypertransfusions”, spongiosa-cavernosa shunts, bed rest etc, etc.

2. **Sickle Cell hematuria.**

Two patients were treated – each with less than a week of HBO. Treatment schedule – 2 ATA 2 hours twice daily in a monoplace chamber without “air breaks”. Hematuria ceased within three days of onset of the Rx. Rationale – cause a vasoconstriction with a decrease in renal blood flow so that hemostasis may occur. The Air Force tried a case in the 1970’s in San Antonio and was not successful – however, they used a different treatment table in a multiplace chamber with “air breaks”. Should any of your contacts in Georgia be inclined to try this – please have them contact me for a discussion on the latter failure.

3. **Sickle Cell Crisis.**

Understand you will soon be in receipt of our one published article in this formidable condition.

Importantly, HBO as to my knowledge is only palliative in these Sickle Cell conditions and does not prevent recurrences. However, *it may reduce the cost of care!*

Thank you, for your interest in this despicable disease:

GB Hart MD FACS



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1. Cutaneous, decubitus, and stasis ulcers. (176 Medline references)
2. Chronic peripheral vascular insufficiency. (50 Medline references)
3. Anaerobic septicemia and infection other than clostridial. (84 Medline references)
4. Skin burns (thermal). (42 Medline references)
5. Senility. (3 Medline references)
6. Myocardial infarction. (heart attack) (110 Medline references)
7. Cardiogenic shock. (heart pumping is inadequate) (15 Medline references)
8. Sick cell anemia. (sickle-shaped red blood cells block circulation) (16 Medline references)
9. Acute thermal and chemical pulmonary damage, i.e., smoke inhalation with pulmonary insufficiency. (77 Medline references)
10. Acute or chronic cerebral vascular insufficiency. (118 Medline references)
11. Hepatic necrosis. (7 Medline references)
12. Aerobic septicemia. (2 Medline references)
13. Nonvascular causes of chronic brain syndrome (Pick's disease, Alzheimer's disease, Korsakoff's disease). (6 Medline references)
14. Tetanus. (36 Medline references)
15. Systemic aerobic infection. (39 Medline references)
16. Organ transplantation. (192 Medline references)
17. Organ storage. (13 Medline references)
18. Pulmonary emphysema. (18 Medline references)
19. Exceptional blood loss anemia. (82 Medline references)
20. Multiple Sclerosis. (96 Medline references)
21. Arthritic Diseases. (38 Medline references)
22. Acute cerebral edema. (24 Medline references)

When I first reviewed the "Noncovered Conditions" list in July, 2000, the eighth one down caught my eye. Sick cell anemia. People of color, people of African descent get sickle cell. I live in Dekalb County, Georgia--which is predominantly African-American. In the summer of

2000, my U.S. Representative was Cynthia McKinney, always a very outspoken critic of the US government and some would say particularly partisan when it comes to any and all issues involving African-Americans. I wanted to present the sickle/HBOT data to Cynthia McKinney so she would in turn light a fire under Georgia Medicaid to treat sickle cell kids with off-label HBOT.

Then, once we returned to our hearing we could point out that Georgia Medicaid was already treating children with off-label hyperbaric oxygen. First I had to get sickle documentation, but I had no idea where to look. I started with a post on the old HBO chat room. I received several responses, and each one said a Dr. George Hart had done some research on sickle cell and hyperbaric oxygen.

Members of the chat room said that Dr. Hart was at Long Beach Memorial Hospital in San Diego. I searched the internet, got a phone number, called and left a series of voicemails. After receiving no responses to my inquiries, I called again. Still no reply. I called thirteen more times. Finally somebody answered and said they would give my number to Dr. Hart. I waited. Two weeks, maybe three. I called back. A secretary answered and said she remembered my 15 previous calls. She said she had given my message to Dr. Hart, but he was retired. I scoured the Internet and came across his home number and I left him a message. No responses, so I called back. I called again later that day and Mrs. Hart answered and she got him on the phone.

He said he'd take the call "downstairs, in my office." He sounded nice. Gentle. Patient. Kind. The warmth in his voice surrounded like an authority built on a lifetime of experience. He had done work on sickle cell and hyperbaric oxygen therapy. In 1991 the Journal of Hyperbaric Medicine published his "Amelioration of Sickle Cell Crisis With Intensive Hyperbaric Oxygen."

Paragraph 5 of the Medicaid law says kids must have whatever is "necessary to correct or ameliorate" and the first word in Dr. Hart's paper was Amelioration. This was perfect.

Then Dr. Hart said; "Hyperbaric oxygen also works for sickle cell priapism.

David Freels: "What's that?"

Dr. Hart:

"The penis stays in a perpetually erect state at two or three times its normal size. It stays that way for weeks and even months at a time. Most of the time they die and nothing can be done."

David Freels: "You're kidding."

Dr. Hart:

"No, it's a despicable disease. We treated a priapism case with 2 atmospheres hyperbaric oxygen twice a day in a monoplace chamber. It was completely resolved in 2 weeks and the patient had been hospitalized for over 9 months for this. They'd given the patient I don't know how many transfusions."

"I've also used hyperbaric oxygen therapy for sickle cell hematuria."

David Freels: "Hematuria?"

Dr. Hart:

Blood in the urine. Again, 2 atmospheres hyperbaric oxygen twice a day in a monoplace chamber. Resolved in 3 days. "What's your interest in sickle cell anemia?"

Are you a physician?"

David Freels:

"Uh, no sir. This might sound kind of confusing. I don't know if you know this, but Hyperbaric Oxygen Therapy is governed by the Health Care Financing Administration--you know, HCFA. See, HCFA has this list of what they call 'covered indications' for hyperbaric oxygen. For some strange reason they have a second list too. It's titled 'Noncovered Conditions' and says, 'No program payment may be made for HBO in the treatment of the following conditions'. Number 8 on the "Noncovered" list is 'sickle cell anemia'."

Dr. Hart:

"That's true, but what's your interest in sickle cell anemia?"



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David Freels:

"I'm not so much interested in sickle cell as I'm interested in the "Noncovered" list. I'm actually more interested in number 10, 'acute or chronic cerebral vascular insufficiency'. You see my wife and I are the parents of a brain-injured child. He's had 42 treatments of hyperbaric oxygen, and we'd like to get him some more." (see Volume I, Issue VI, p.33)
There was a pause.

Dr. Hart:

"How did your son do with the HBO?"

David Freels: "He did great."

Dr. Hart: "Like what?"

David Freels:

"Much better speech. Greatly improved fine motor skills. On Father's Day he said, 'Look Dad,' and stabbed a bean with his fork and then put it in his mouth. He can now feed himself for the first time. He used to speak in two-word couplets. Now he talks in sentences. Paragraphs even. He initiates conversation."

Dr. Hart: "Hmm. What was your protocol?"

David Freels:

"One hour at one point seven five atmospheres, once a day, five days a week. He had 42 treatments. We did SPECT scans too."

Dr. Hart: "What did the SPECT show?"

David Freels:

"His cerebral blood flow improved 25.4%."

Dr. Hart:

"We're doing a double-blind controlled study of hyperbaric oxygen on cerebral palsy."

David Freels:

"Really? I thought you were retired."
There was a slight pause.

Dr. Hart: "I'm doing this."

David Freels:

"Are you seeing some good results?"

Dr. Hart: "I can't say."

David Freels:

"How many treatments have you done?"

Dr. Hart:

"We're about half way through."

David Freels:

"No kidding. That's great. You're seeing some good stuff then, huh?"

Dr. Hart: "I can't say."

David Freels:

"That's okay. I know you are."

Dr. Hart: "How do you know that?"

David Freels:

"It's something like over 90% of every kid who gets HBO has some kind of improvement. Some say it's closer to 95%."

Dr. Hart: "Who says that?"

David Freels: "Dr. Harch. Paul Harch."

Dr. Hart: "You know Dr. Harch?"

David Freels:

"He's great. I think he ought to get the Nobel Prize."

Dr. Hart:

"Harch isn't going to get credit for this."

David Freels:

"I thought you said it wasn't working?"

Dr. Hart:

"I didn't say that. I just said I couldn't say."

David Freels:

"You just did. You know Dr. Harch is a big admirer of yours."

Dr. Hart: "How do you know that?"

David Freels:

"We talk. It's taken me awhile to track you down. You're a hard man to get a hold of. Dr. Harch knows a lot of people, and I figured he might know you, so I asked him."

Dr. Hart: "How do you know Harch?"

David Freels:

"Dr. Harch spoke as an expert witness at our first Medicaid hearing date a few weeks ago."

Dr. Hart: "Medicaid?"

David Freels:

"Jimmy is a Medicaid recipient because of his, uh, situation, and according to the federal Medicaid law for children, Georgia Medicaid should be paying for more hyperbaric oxygen. They've denied us because they go by Medicare's HBO policy."

Dr. Hart:

"Are they saying it's experimental and investigational?"

David Freels:

"And not medically necessary, and not the standard of medical practice."

Dr. Hart: "They're right."

David Freels:

"Yeah, but that's not what the Medicaid law says."

Dr. Hart: "What's it say?"

David Freels:

"It says, here I'll read it to you. These kids are supposed to get 'such other necessary health care, diagnostic services, treatment, and other measures to correct or ameliorate defects and physical and mental illnesses and conditions discovered by the screening services, whether or not such services are covered under the State plan.'"

Dr. Hart: "So?"



David Freels:

"It doesn't say 'medically necessary'; it says "whatever is...necessary to correct or ameliorate."

Dr. Hart:

"Hmmm. So what's sickle cell got to do with this?"

David Freels:

"The hearing reconvenes the latter part of September 2000, and I'm trying to get ready for it. See, I live in Atlanta, and there's probably a 65% black population here. My congress-person is a lady named Cynthia McKinney, who's very good at bringing in national and international media attention to any situation or circumstance where she feels black people are exploited; particularly by the government. I think she does lunch with Louis Farrakhan. I'd like to bring this sickle cell and hyperbaric oxygen thing to her attention, that way some other Georgia Medicaid kids can get some off label HBO from the "Noncovered" list and we can use that in our hearing. You know, what's good for the goose is good for the gander."

Dr. Hart:

"That's not a bad idea. Do you know where the "Noncovered" list came from?"

David Freels:

"I don't know. The UHMS I guess."

Dr. Hart:

"Sort of. It came from a committee the Social Security Administration put together back in the early 1970's when they were deciding what hyperbaric oxygen would be used for."

David Freels:

"Really. How do you know that?"

Dr. Hart:

"I was chairman of the committee."

David Freels:

"Wow. Are you serious? Really?"

Dr. Hart:

"Really. I used to be president of the UHMS."

David Freels:

"Where did the second list come from, the "Noncovered" list?"

Dr. Hart: "It came from me."

David Freels: "You're kidding. Why?"

Dr. Hart:

"I told Social Security that I didn't want to be on the committee, but they kept asking. So finally I said yes. Under one condition."

David Freels: "What?"

Dr. Hart:

"They let me add the "Noncovered" list."

David Freels: "Why?"

Dr. Hart:

"Because one day this guy came to my office. He was a very, very, very senior government official, whose name you would recognize. He came into my office and pointed his finger at me and said, 'You will not, under any circumstance, approve Hyperbaric Oxygen Therapy for stroke.'"

"Why not, I said. It works."

"I don't care," he said, 'I'm not going to let you do it.'"

"But it works, I said. You know it works."

"I don't care, he said, it'll break the bank, and I'm not going to let you do it. You're not going to approve this for stroke, and that's an order."

"An order?" I asked."

"I was an officer in the United States Navy. I'm retired now. I was given an order, and I had to obey it."

David Freels:

"What did he mean by 'break the bank'?"

Dr. Hart:

"He thought the country would go bankrupt if we treated everybody who had a stroke. At that time there were probably less than a hundred chambers in the whole country. Maybe just 30 or 40."

David Freels:

"Who was this who gave you the order?"

Dr. Hart:

"I can't say, but you'd recognize the name if I told you. Listen, I've treated so many retired Navy officers who've stroked. I've put them in the chamber and they've made a complete recovery."

David Freels:

"So Hyperbaric Oxygen Therapy works for stroke?"

Dr. Hart:

"Of course it works. It works for stroke better than just about anything else, except maybe DCS."

David Freels: "DCS?"

Dr. Hart:

"Decompression sickness. The bends. It hits scuba divers. Listen, if they made HBO available for everything it works for, three-fourths of the nursing homes in this country would shut down inside of six months. Everybody would go home. They wouldn't need them. It works for stroke, MS, Parkinson's, Alzheimer's--Alzheimer's, let me tell you. See, there's a very real, very serious disease where the vascular tissue breaks down in the brain with age. Creates dementia, senility. What everybody now calls Alzheimer's."

David Freels:

"Hyperbaric Oxygen Therapy works for Alzheimer's?"

Dr. Hart:

"Of course it does. You just can't wait until they're blithering idiots before you give it to them. You've got to give it to them early enough in the disease process. If you wait until their brains are mush it's not going to do them any good at all."

David Freels:

"Do you realize what you're telling me? You're telling me there really was somebody on the grassy knoll in Dallas."

Dr. Hart:

"Listen, I spent my entire career working



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for the government. Anybody who works for the government as long as I did can tell you stories like this. I don't care what department or agency they work for. Everybody could tell you something like what I've just told you."

David Freels:

"Can you give me an affidavit. You know, put into writing what you just told me. We've got this hearing coming up, and I know what you just told me would be very helpful."

Dr. Hart:

"No I won't do that, and if anybody asks me about what I've just told you, I'll deny every bit of it."

David Freels: "Why?"

Dr. Hart:

"Look, I was given an order. If I violated that order I would have been guilty of insubordination. I wasn't going to do that. Instead, I agreed to serve on Social Security's Hyperbaric Oxygen Committee only if they would let me put out the two lists: The covered list and the "Noncovered" indications."

David Freels:

"But what good does that do?"

Dr. Hart:

"They were going to approve it for what they were going to approve it for whether I was on the committee or not. When they kept asking me to chair the committee, I insisted on the second list because I wanted people to question why it wasn't approved for things beyond just the covered indications. The only way I could guarantee that questioning would take place was to create the second list, to spell it out. Hyperbaric Oxygen Therapy has such a wide range of uses I wanted people to say 'why is it not covered for this when it works for that?'"

David Freels: "Like sickle cell anemia?"

Dr. Hart: "Yes."

David Freels:

"And cerebral vascular insufficiency?"

Dr. Hart: "Exactly."

David Freels:

"But the "Noncovered" list is just an off label list?"

Dr. Hart: "True."

David Freels:

"And 75% of all medications are prescribed off-label--"

Dr. Hart: "True."

David Freels:

"In pediatric neurology, it's right at 100% of everything prescribed for brain-injured children is prescribed off-label."

Dr. Hart: "Doesn't surprise me."

David Freels:

"Maybe you don't realize this, but when people see something on the "Noncovered" list, you know, the people in the hospitals where most of the chambers are, and they see that list coming from the federal government, they're not seeing that list as being off-label, they see it as illegal to provide hyperbaric oxygen for any disease on the "Noncovered" list. They literally think they would be breaking a federal law if they gave hyperbaric oxygen therapy to somebody who's had a stroke." There was silence on the other end of the line.

"Dr. Hart?"

Dr. Hart:

"You may be right, but I can't help that. Look I've made it my life's work to prove Hyperbaric Oxygen Therapy works for as many things as I could on the "Noncovered" list. That's been the primary focus of my research. I don't know what else I can do."

David Freels:

"Why don't you tell somebody what you just told me? This is a pretty amazing story, but I'm nobody. Why don't you sit down with Mike Wallace on 60 Minutes or something."

Dr. Hart:

"I'm not going to do that. I can't do that. I had to follow orders."

David Freels:

"That was 30 years ago. What if you spoke Congressional hearing, where your identity was hidden and you were given some sort of, I don't know, protection. Immunity from whatever. I don't remember what they call it. Whatever Oliver North was given."

Dr. Hart:

"I'll say something at the right time in the right place, but not until then."

David Freels:

"Dr. Hart, I just called today to ask you about your sickle cell research. Never in a million years did I ever expect this. But look, I've got a brain-injured kid. What you've just told me, if I could bring back into our hearing what you've just told me, we'd win, hands down. Especially if you've got the documentation to back up everything you've said, and I presume you do. Every brain-injured kid in the country would win. Every kid around the world, not to mention stroke, MS, & Alzheimer's. What you've just told me should be on the cover of Time Magazine, Newsweek, CBS, NBC, CNN, you name it. But if I told anybody about this it would sound like something from the National Enquirer. You need to tell this story to somebody besides me."

Dr. Hart:

"I will. When the time is right."

David Freels:

"So, can you still send me some stuff on sickle cell?"

Dr. Hart: "Sure."

David Freels: "Well, thank you."

Dr. Hart:

"Remember. I'll deny this if anybody asks me."

David Freels:

"Well, if I tell anybody, just don't sue me."