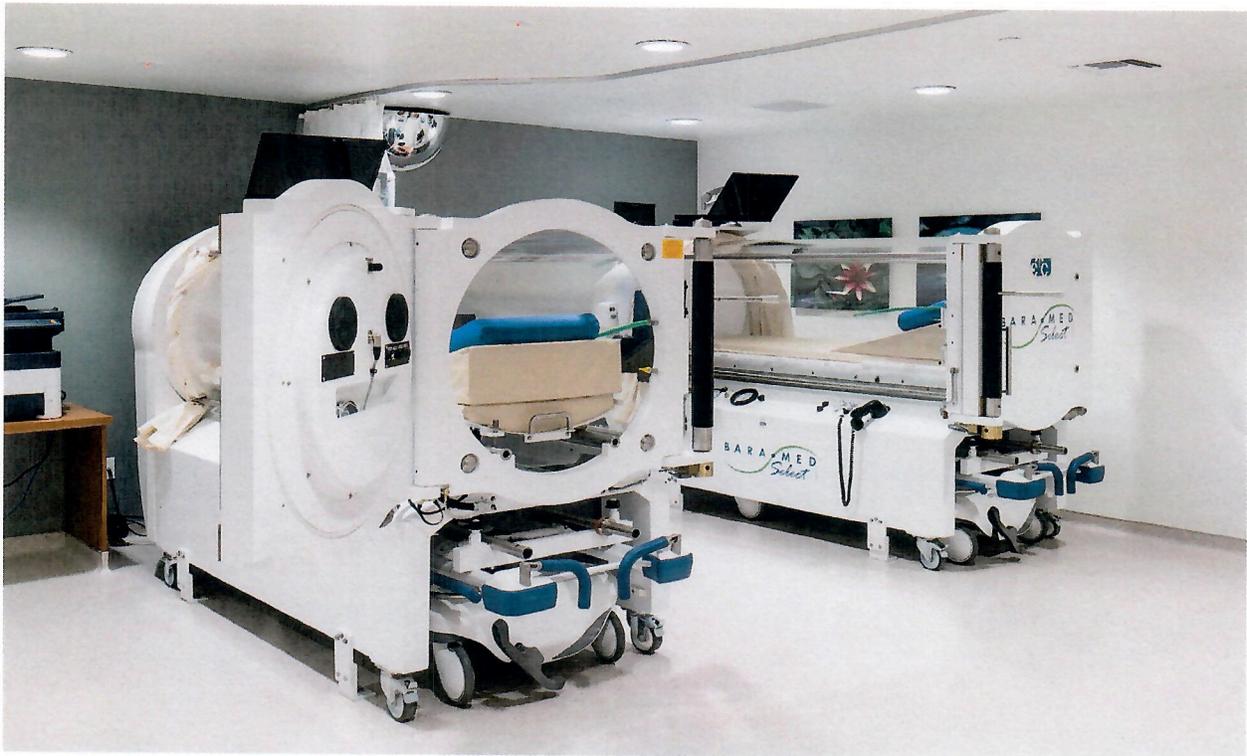


Our Veterans Have Earned Easy Access to Diabetic Limb-Saving Care:

Cost Benefit Analysis of Hyperbaric Oxygen Therapy for Veteran Diabetic Foot Ulcers (DFUs) in the VA and Tricare Health System



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Executive Summary

“All that a man hath he will give his life for his country ... the soldier puts his life at stake, and often yields it up in his country’s cause. The highest merit, then, is due the soldier” (Abraham Lincoln March 1864).

The soaring diabetes rates, and the associated lower limb amputations, across the globe have fueled prosthetics and wheelchair industries. There are **2.1 million people** living with limb loss in the USA, and that number is *expected to double* by 2050.¹ Our Veteran population is not immune to this reality. Diabetes is one of the most widespread chronic diseases in the United States yet is also one of the most ignored and underdiagnosed. The civilian population has relatively easy access to limb saving treatments including hyperbaric oxygen through commercial payers, Tricare, Medicare, and Medicaid. Hyperbaric Oxygen Therapy (HBOT) is a therapy proven to reduce amputations in patients with diabetic foot ulcers (DFU’s) and is an approved indication by the FDA. CMS and even, Tricare. Our Veterans deserve the same ease of access to this life saving care, which is not the current situation. Despite recent efforts by the VA to improve access to community available care, the referral and reimbursement process continues to be overly burdensome and because of this, limits access. Providing routine HBOT services to diabetic DFU patients in both the VA, DoD and civilian communities is a proven treatment modality to improve DFU outcomes and reduce or prevent amputations. A standard course of HBOT has been shown to improve outcomes, reduce the need for amputations, while proving more cost effective than the amputation surgery and associated after-care (rehab, home health, physical therapy, durable medical equipment, and prosthetics). The VA system and Tricare in particular, should be able to realize significant cost savings over the short and long-term with the use of HBOT services for many of the FDA approved indications, but especially with DFU’s as the financial analysis herein shows. HBOT treatments are estimated to be less than 13 percent of the cost for surgical, inpatient hospital stay and cost of care expense for DFU amputations (Table 8). That is the financial reality. Perhaps a more important reality is the decline in quality and length of life associated with loss of a limb.

In 2022, it is estimated the VA Diabetic Foot Ulcer (DFU) Lower Limb Amputations (LLAs) will have a \$1.8 billion annual economic impact (Table 1). The surgical cost estimate of over \$491 million and the cost of care after surgery estimate of \$536 million accounts for approximately 65 percent of the total amputation cost in 2022 (Table 1). With an estimate of over 3.1 million diabetics in the VA, the projection for the next ten years will be for DFU LLAs to increase substantially from the current VA twenty-year average of 6,032 amputations per year. The cost escalation for surgical procedures and after care will not be sustainable long-term by insurance providers based on current trends. Diabetes and diabetes related lower extremity complications combined account for the third most costly disease burden.² Reducing and

¹ Infor@AccessProsthetics.com; **15 Limb Loss Statistics that May Surprise You, October 18, 2017**

² Lazzarini, P. A., Pacella, R. E., Armstrong, D. G., & van Netten, J. J. (2018). Diabetes-related lower-extremity complications are a leading cause of the global burden of disability. *Diabetic Medicine*, 35(9), 1297-1299. <https://doi.org/10.1111/dme.13680>

sustaining even 50 percent of the amputations by treating with HBOT will have significant quality of life and financial benefits.

Among the overall US population, 2018 estimates were 34.2 million people of all ages, or 10.5 percent of the population had diabetes. An additional 34.1 million adults 18 years or older or 13 percent of all US adults, and 7.3 million adults were not aware or did not report having diabetes.³ Seniors over 65 years of age account for 26.8 percent of the US population with diabetes.⁴ Approximately 50-70 percent of the Veterans enrolled in the Veteran Administration Health network are diabetic. Approximately 25 percent of diabetics will develop a DFU in their lifetime, 56 percent of DFUs will become infected and one in five of those will require an amputation.⁵ Approximately 85 percent of lower limb amputations are preceded by a foot ulcer.⁶ Following Lower Limb Amputation (LLA), 50 percent will undergo contralateral amputation in two-five years. Patients undergoing a bilateral amputation due to a DFU, have a five-year mortality rate higher than rates for breast cancer, colon cancer, and prostate cancer combined.⁷ Amputation is not just a life altering event, it has become a death sentence worse than cancer.

Diabetic Foot Ulcer: Unresponsive to Conventional Therapy.



1 Day Prior to Scheduled Amputation



26 HBOT Treatments



50 HBOT Treatments

**Hyperbaric Oxygenation prevents
Approximately 50% of Lower Limb
Amputations (LLA's) in diabetic
patients. VA Average 6,032+
AMPUTATIONS Per Year Since 2002,
Over 136K, 71% die within 3 Years**

“The estimate in the US in 2007 was \$18.9 billion spent on the care of diabetic foot ulcers and \$11.7 billion on lower extremity amputations. It becomes a death sentence for 70.1 percent of DFU Veterans who are told amputation is the only option remaining. It is estimated lifetime healthcare costs for people with limb loss is \$509,275 compared to \$361,200 for people without

³ Cdc.gov; National Diabetes Statistics Report 2020; Estimates of Diabetes and Its Burden in the United States

⁴ Ibid.

⁵ Amputation Prevention Center at Sherman Oaks Hospital; Diabetic Foot Ulcer Protocols; Lee C Rogers, D.P.M.

⁶ Infor@AccessProsthetics.com; 15 Limb Loss Statistics that May Surprise You, October 18, 2017

⁷ Infor@AccessProsthetics.com; 15 Limb Loss Statistics that May Surprise You, October 18, 2017

limb loss.⁸ In 2013 numbers it was estimated hospital charges for patients who underwent amputation totaled \$8.7 billion. The estimated cost to American private and public insurance agencies is \$12 billion annually. We estimated since 2002 through 2022, slightly over 148,000 DFU amputations in the VA at an estimated cost of \$9.8 billion for surgical procedures.. This is in addition to another \$383.8 million in hospital after surgery costs for the average stay of 11-days (Table 1). Over 102,000 Veterans are estimated to have died within 3-years. The cost of care after amputation surgery is estimated to be \$536.3 million in 2022 dollars (Table 1). When you dovetail in wheelchair costs at \$117.1 million and prostheses cost at \$58.3 million, the cost to treat DFUs with HBOT becomes an easy business decision. However, this should not be a financial decision alone.

The human costs of amputation are life changing. Most authors find the return-to-work rate for amputees to be about 66% (from 43.5 to 100% for participants after lower limb amputation and 53–100% for people after upper limb amputation) ⁹Considerations related to return-to-work depends on general factors, such as age, gender and educational level; factors related to impairments and disabilities because of amputation (amputation level, multiple amputations, co-morbidity, the reason for amputation, persistent stump problems, the time from the injury to obtaining a permanent prosthesis, wearing comfort of the prosthesis, walking distance and restrictions in mobility; rehabilitation; factors related to prosthesis; and factors related to work and policies (salary, higher job involvement, good support from the implementing body and the employer and social support network).Amputation wounds generally heal in four to eight weeks on average. Being permanently disabled and unemployed or unemployable is devastating.

Mortality rates following amputation patients ranges from 13 to 40 percent in year one, 35-70 percent in three years, and 38-80 percent in five years, making amputation worse than most malignancies.¹⁰Typical complications associated with amputations consist of heart problems such as heart attacks, deep vein thrombosis (DVT), slow wound healing and wound infection requiring a second amputation, pneumonia, and stump or “phantom limb” pain. Physical rehabilitation is an important aspect after amputation, but it can be long, difficult and a frustrating process for most patients.

The additional cost incurred include walking aids, wheelchair or scooter, prostheses limbs, if affordable or covered under medical insurance, assessing care and support needs, wheelchair ramps or stairlifts, special designed vehicles, physiotherapy denial, physical therapy, emotional stress such as depression, anxiety, grief and suicidal ideation, and PTSD. All these factors compound the financial impact over the expected average 2-5-year lifespan after amputation. We did not include all these additional humanistic costs into the analysis.

Since 2002, hyperbaric oxygen therapy has helped prevent amputations across America. Foot wounds are one of the most common complications of diabetes and are responsible for

⁸ [Infor@AccessProsthetics.com](https://www.accessprosthetics.com): **15 Limb Loss Statistics That May Surprise You, October 18, 2017**

⁹ Researchgate.net; Return to Work After Amputation, January 1970DOI:[10.1007/978-0-387-87462-3_7](https://doi.org/10.1007/978-0-387-87462-3_7); In book: *Amputation, Prosthesis Use, and Phantom Limb Pain* (pp.101-114)

¹⁰ Ncbi.nlm.nih.gov; Factors affecting lifespan following below-knee amputation in diabetic patients; October 5, 2017: 393-397

substantial morbidity.¹¹ Studies involving a significant number of patients have shown a high success rate in patients who had been unsuccessful with other modes of therapy.¹² “Of 1984 study records screened, 14 studies (768 participants) including twelve RCTs, and two CCTs were included as per inclusion criteria. The results with pooled analysis have shown that HBOT was significantly effective in complete healing of diabetic foot ulcer and reduction of major amputation.”¹³ This review provides evidence that hyperbaric oxygen therapy is safe and effective as an adjunct treatment measure for the foot ulcers and avoiding amputations inside and out of the VA.

The VA does not have an HBOT capability. Our research did not reveal widespread HBOT prescription and use by VA network providers. We also could not identify where DFU’s are being routinely treated outside of the VA in the civilian HBOT facilities. In 2018 there were over 1,156 hospitals across the country equipped with hyperbaric oxygen chambers, and approximately 120 more private clinics. Assuming two monoplace chambers per facility, we estimate over 2,500 HBOT chambers available in the US. We did not include the facilities equipped with multi-place chambers to accommodate 2-20 patients at a time. There is adequate existing capacity for all DFU Veterans to be treated under the current VA policy and guidelines. With significant reduction in amputations being realized from treating with HBOT, the potential cost savings would be significant using the FDA, CMS, and Tricare approved treatment modality.

Hyperbaric Oxygen Therapy (HBOT) is approved by the FDA and CMS for 14 indications. Tricare has approved approximately nine of these treatment modalities, reflecting an industry and medical acceptance and use for decades. The medical benefits to patients across all approved indications has improved or saved lives. The approved HBOT indications have reduced long-term cost versus the conventional non-HBOT treatment approach over the full spectrum of FDA indications.

Hyperbaric Oxygen Therapy for DFUs has been an approved indication for almost two decades. It is also a cost-effective, proven treatment to reduce amputations, avoid related associated high post-surgery health costs, and significantly improve quality of life and length of Veterans lives. On the business side, providing HBOT outsource services and making treatments widely available to the VA patients and military service members, it will produce a high return on investment for Tricare providers. We can substantially lower overall healthcare costs while saving lives. Because of these financial, and more importantly human benefits, we ask that the VA system improve and actively promote access to community based hyperbaric centers to help save the lives and limbs of our Veteran population.

¹¹ Washington State Health Care Authority; Hyperbaric Oxygen Therapy (HBOT) for Tissue Damage, Including Wound Care and Treatment of Central Nervous System Conditions; Final Evidence Report; 2013

¹² O2wny.com; Can HBOIT Help You Avoid Amputation? Craig Danehy, July 23, 2018

¹³ Ncbi.nlm.nih.gov; Efficacy of hyperbaric oxygen therapy for DFU, a systematic review and meta-analysis of controlled clinical trials;2021

TABLE 1

Cost Benefit Analysis of HBOT for DFU versus Amputation (Cost estimates based on average of 6,032 Veteran amputations per year)

Estimated Annual Amputation Cost Impact

1. Total estimated annual amputation surgical cost since (\$9.8 billion/20 years= average cost year)	\$491.0 Million
2. Total estimated inpatient hospital stays cost (11 days)	\$383.9 Million
3. Total estimated three-year wheelchair cost	\$225.6 Million
4. Total estimated 2022 VA Cost of Care DFU patients	\$536.3 Million
5. Total estimated 2022 average annual Protheses costs	\$58.3 Million
6. VA and Social Security disability payments per year	\$111.9 Million
7. Total estimated DFU amputations annual impact cost	\$1.8 Billion

Estimated Annual HBOT Treatment Cost Wagner Grade III

1. Estimated annual HBOT treatment cost 6,032 Vets (HBOT treatments based upon 2.0-2.5 ATA pressure For 120 minutes per day at \$119 per 30 min segment And 6,032 Veterans per year)	\$181.2 million
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Estimated Annual Cost Savings Impact

1. Estimated HBOT percent treatment to amputation	10%
2. Estimated annual cost savings (Minus disability payments)	\$1.68 Billion

Notes

Note 1: 1989-1998 data, Journal of Rehabilitation Research and Development, Vol 37, No 1, January/February 2000, Pages 23-30, Trends in lower limb amputation in the VA Health Administration

Note 2: FDA and CMS approved HBOT for diabetic Foot Ulcers in 2002 for DFU Wagner Grade III or higher

Note 3: Surgical cost escalated at 3.24% per year based on 114-year average US inflation rate

Note 4: Three-year mortality rate after amputation is 70.9% of patients

Note 5: 60-70% of hospitalized Veterans in US have diabetes

Note 6: Detailed analysis spreadsheets are available upon request to substantiate the herein above costs