

Dehydrated Human Amnion Chorion Membranes To Treat Venous Leg Ulcers (VLUs) In The U.S. Medicare Population: A Cost-Effectiveness Analysis

WH Tettelbach, MD^{1,2,3,4,*}; V Driver, DPM^{6,7}; A Oropallo, MD^{8,9}; MR Kelso¹⁰, RN; JA Niezgodza¹¹, MD; N Wahab, MD^{12,13,14,15}; JL De Jong, MS⁵; Brandon Hubbs, MS⁵; RA Forsyth^{5,16}, PhD; GA Magee, MD¹⁷; William V Padula, Ph.D.^{18,19,20}

OBJECTIVE

Facing the challenges of rising costs associated with treating chronic wounds, the objective of this analysis was to evaluate the cost-effectiveness of Dehydrated Human Amnion Chorion Membrane (DHACM) in Medicare enrollees who develop a venous leg ulcer (VLU).

METHODS

This retrospective economic evaluation used a four-state Markov model to simulate the disease progression of VLUs for patients receiving advanced treatment (AT) with DHACM or no advanced treatment (NAT) over a three-year time horizon from a U.S. Medicare perspective (Figure 1). DHACM treatments were assessed when following parameters for use (FPFU), whereby applications were initiated 30-45 days after the initial VLU diagnosis claim, and reapplications occurred on a weekly to biweekly basis to the completion of the treatment episode. The cohort was modeled on the claims of 530,220 Medicare developed a VLU between 2015 and 2019. Direct medical costs, quality-adjusted life years (QALYs), and the net monetary benefit (NMB) at a willingness-to-pay threshold of \$100,000/QALY were applied. Univariate and probabilistic sensitivity analyses (PSA) were performed to test the uncertainty of model results.

RESULTS

Cohorts were evaluated for the frequency of comorbidities in the chronic and complex health states. Notably, all the top comorbidities increased in the complex VLU state. The symptom frequency of pain increased more than 3-fold

Author Affiliations

- Barrow Neurosurgical Institute, Department of Neurosurgery, Brain & Spine, Phoenix, AZ, US.
- RestorixHealth, Metairie, LA, US.
- Duke University School of Medicine, Department of Anesthesiology, US.
- American Professional Wound Care Association, US.
- MIMedx Group Inc., GA, US.
- Wound Care and Hyperbaric Centers at INOVA Healthcare, US.
- Wound Care Collaborative Community, US.
- Comprehensive Wound Healing Center, US.
- Hyperbarics at Northwell Health, US.
- Wound Care Plus, LLC, MO, US.
- AZH Wound & Vascular Centers, US.
- Wound Care Experts, NV, US.
- HCA Mountain View Hospital, US.
- Roseman University College of Medicine, US.
- Common Spirit Dignity Hospitals, US.
- Department of Biology, San Diego State University, US.
- Keck School of Medicine, University of Southern California, US.
- Stage Analytics, Baltimore, MD, US.
- Department of Pharmaceutical & Health Economics, Mann School of Pharmacy & Pharmaceutical Sciences, University of Southern California, Los Angeles, CA, US.
- The Leonard D. Schaeffer Center for Health Policy & Economics, University of Southern California, Los Angeles, CA, US.

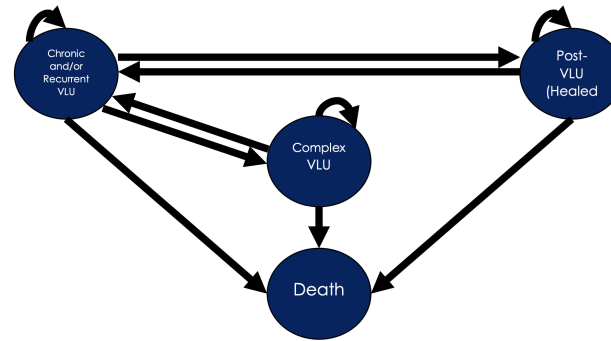


Figure 1: Markov model diagram. Four-state Markov model. Treatment arm 1: intervention with DHACM following parameters for use (FPFU) or treatment arm 2: no advanced therapy (NAT). VLUs can remain chronic, become healed (Post-VLU), or develop complications (Complex VLU) after receiving treatment. Healed VLUs can remain healed or recur (Recurrent VLU). Complex VLUs can remain complex or return to chronic. All health states transition to death throughout the time horizon.

RESULTS

(9.5% to 31.9%). The overall Charlson Comorbidity Index score (CCI, a ten-year mortality prediction for a patient based on their comorbidities) between the chronic and complex health states increased 29% (+0.6 CCI) for patients receiving NAT, while patients receiving DHACM FPFU had an increase in their CCI score of 68% (+1.3 CCI). The use of DHACM FPFU demonstrated further reductions in hospital utilization in relation to NAT. Hospital resource usage increased by 6-10X in the complex VLU state compared to chronic VLUs without an infection (Figure. 2). DHACM applied FPFU dominated over NAT, yielding a lower per-patient cost of \$170 and an increase of 0.010 QALYs over three years. The resulting NMB was \$1,178 per patient in favor of DHACM FPFU over the same time horizon (Table 2). The rate of VLU recurrence had a notable impact on model uncertainty. In the PSA, DHACM FPFU was cost-effective in 63.01% of simulations at the \$100,000/QALY threshold. DHACM applied FPFU dominated over NAT, yielding a lower per-patient cost of \$170 and an increase of 0.010 QALYs over three years over NAT, yielding a lower per-patient cost of \$170 and an increase of 0.010 QALYs over three years. The resulting NMB was \$1,178 per patient in favor of DHACM FPFU over the same time horizon (Table 1).

Following parameters for use (FPFU) to treat hard-to-heal wounds is defined as initiating a CAMP within 30 - 45 days of the initial claim submission and once initiated the CAMP is applied routinely within the range of every 7 to 14 days.

William Tettelbach corresponding author: tarpon@xmission.com
DHACM = EPIFIX (MIMedx Group, Inc, Marietta, GA, US)

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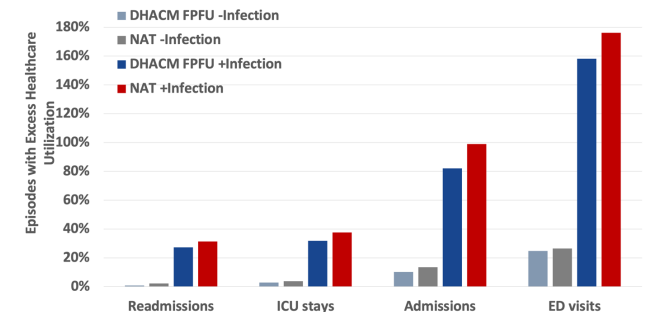


Figure 2: Hospital utilization increases when patients have a complex venous leg ulcer (VLU). Comparisons of episodes with a VLU (blue bars) or complex VLU (red bars) treated with DHACM FPFU (light colors) or NAT (dark colors) were tracked for their utilization of hospital resources (readmissions, ICU stays, admissions, and ED visits). Significance was observed when comparing all DHACM FPFU (light bars) to all NAT (dark bars) for readmissions (p=0.03575), ICU stays (p=0.00062), Admissions (p=0.00001), or ED visits (p=0.00036).

The rate of VLU recurrence had a notable impact on model uncertainty. In the PSA, DHACM FPFU was cost-effective in 63.01% of simulations at the \$100,000/QALY threshold.

Table 1: Cost-effectiveness and budget impact results

Cost-Effectiveness Results (Per Patient)	Year 1	Years 1-2 Cumulative	Years 1-3 Cumulative
	Cost of DHACM, \$USD	31,338	44,279
Cost of NAT, \$USD	30,872	44,418	56,764
Cost difference, \$USD	466	-139	-170
QALYs of DHACM	0.708	1.395	2.048
QALYs of NAT	0.699	1.385	2.038
QALYs difference	0.009	0.010	0.010
ICER (\$/QALY)	51,059	Dominant	Dominant
NMB at \$100,000/QALY WTP threshold, \$USD	446	1,142	1,178
Budget Impact for One Million Members in Year One			
Cost difference for 753 people at risk, \$USD			100,268
Cost difference per one-million-member health plan, \$USD			0.10
Difference per member per month, \$USD			0.008

NAT—no advanced therapy; QALY—quality adjusted life year; ICER—incremental cost-effectiveness ratio; NMB—net monetary benefit; WTP—willingness to pay; Model assumes 0.251% incidence of venous leg ulcers of which 30% become chronic and a 28.6% market share of DHACM; all calculations have been rounded to the nearest second or third place

CONCLUSION

DHACM FPFU was the dominant strategy compared to NAT, as it was cost-saving and generated greater QALYs over three years from the US Medicare perspective. A companion VLU Medicare outcomes analysis revealed patients who received a CAMP compared to patients who received NAT had the best outcomes.⁶ Given the added clinical benefits to patients at lower cost, providers should consider DHACM FPFU for patients suffering with hard-to heal VLUs.