Cost-Effectiveness of Dehydrated Human Amnion Chorion Membrane Allografts in the Treatment of Lower Extremity Diabetic Ulcers

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SAWC Fall 2022

INTRODUCTION

The prevalence of diabetes is increasing in the US; estimated to be >10% of the population with calculated annual costs of $327 billion in 2017.[1] A key driver of costs for patients with diabetes is lower extremity diabetic ulcers (LEDU) which present a substantial financial burden to payers and a disutility burden to patients. Medicare alone spends nearly $20 billion annually on diabetic-related ulcers.[2] Patients with an LEDU face challenges with mobility, the risk of infection, amputation, decreased quality of life (QoL) and a shortened lifespan, all of which are exacerbated following amputations.[3,4] Paradoxically, it is estimated that up to 85% of amputations are avoidable with a holistic multispecialty team approach that incorporates innovative treatments and adherence to treatment parameters.[5]

OBJECTIVE

To evaluate the cost-effectiveness and budget impact of using standard care (No Advanced treatment, NAT) compared to an advanced Treatment (AT), like a Dehydrated Amnion/Chorion Membrane (DHACM) allograft, when Following Parameters for Use (FPFU) in treating Lower Extremity Diabetic Ulcers (LEDUs). FPFU is defined as the initiation of an AT within 30–45 days of a LEDU diagnosis and routine AT applications every 7–14 days during the episode of care.

METHODS

A retrospective analysis of Medicare data files from 2015-2019 was used to generate four propensity-matched cohorts of LEDU episodes. Outcomes for DHACM and NAT such as amputations, and healthcare utilization were tracked from claims codes, analyzed, and used to build a hybrid economic model, combining a one-year decision tree and a four-year Markov model. The budget impact was evaluated in the difference in per member per month spending following completion of the decision tree. Likewise, the cost-effectiveness was analyzed before and after the Markov model at a willingness-to-pay threshold of $100,000 per quality adjusted life year (QALY). The analysis was conducted from the healthcare sector perspective.

RESULTS

In the full dataset, 10,900,127 patients had a confirmed diabetes diagnosis, within which 1,213,614 had a confirmed diagnosis of LEDU (Table 1). Propensity-matched Group 1 was generated from 19,910 episodes which received AT (Figure 1). Only 9.2% of episodes were FPFU while DHACM was identified as the most widely used AT product (Figure 2).

Table 1. Criteria Applied To Identify Eligible LEDU Patients/Episodes

Criteria	Rationale	Number of patients excluded	Number of LEDU patients
Meta-group Exclusions			
• ICD-10 coded diagnosis as a patient with foot ulcer[4]	Consensus definition	9,649,219	1,250,908
• Confirmed diagnosis of Diabetes with a LEDU[4]	Consensus definition	37,294	1,213,614
• LEDU episode started after 10/1/2015	Study focus criteria	124,508	1,089,106
Exclusions based on the wound			
• ICD-10 diagnosis coded as an ulcer above the knee[4]	Consensus definition	8,963	1,080,143
• No defined wound size during run in period	Study focus criteria	762,665	317,478
• Wound depth at bone during run in period	Study focus criteria	20,234	297,244
• Multiple wounds identified during run in period	Study focus criteria	88,756	208,488
Exclusions based on timeline or confounding patient and treatment complications			
• LEDU resolved after 10/2/2019	Period of the Medicare dataset	24,961	183,527
• Episodes with no outpatient claims data	Period of the Medicare dataset	672	182,855
• NAT episodes resolved within 90 days	Not a chronic foot ulcer	89,077	93,778
• Patients receiving hemodialysis (only stage 5)[4]	Confounding comorbidity	13,400	80,378
• Patients that died within 90 days of the last clinic visit	Confounding comorbidity	7,027	73,351
• Patients with no payment or demographic info	Include validated claims	1,130	72,221
• Patients treated with products outside the scope of study	Confounding treatment	2,310	69,911

1,250,908 Patients with LE Ulcers

69,911 LEDU patients

Propensity-matched Group 4 was limited by the 590 episodes that used DHACM FPFU (Figure 1). On average, AT was initiated about 80 days into an episode of care in contrast to only about 35 days for AT episodes that were FPFU. Episodes using DHACM FPFU also had the shortest average length of treatment.

Figure 1: Consort Diagram of Propensity Matched Groups

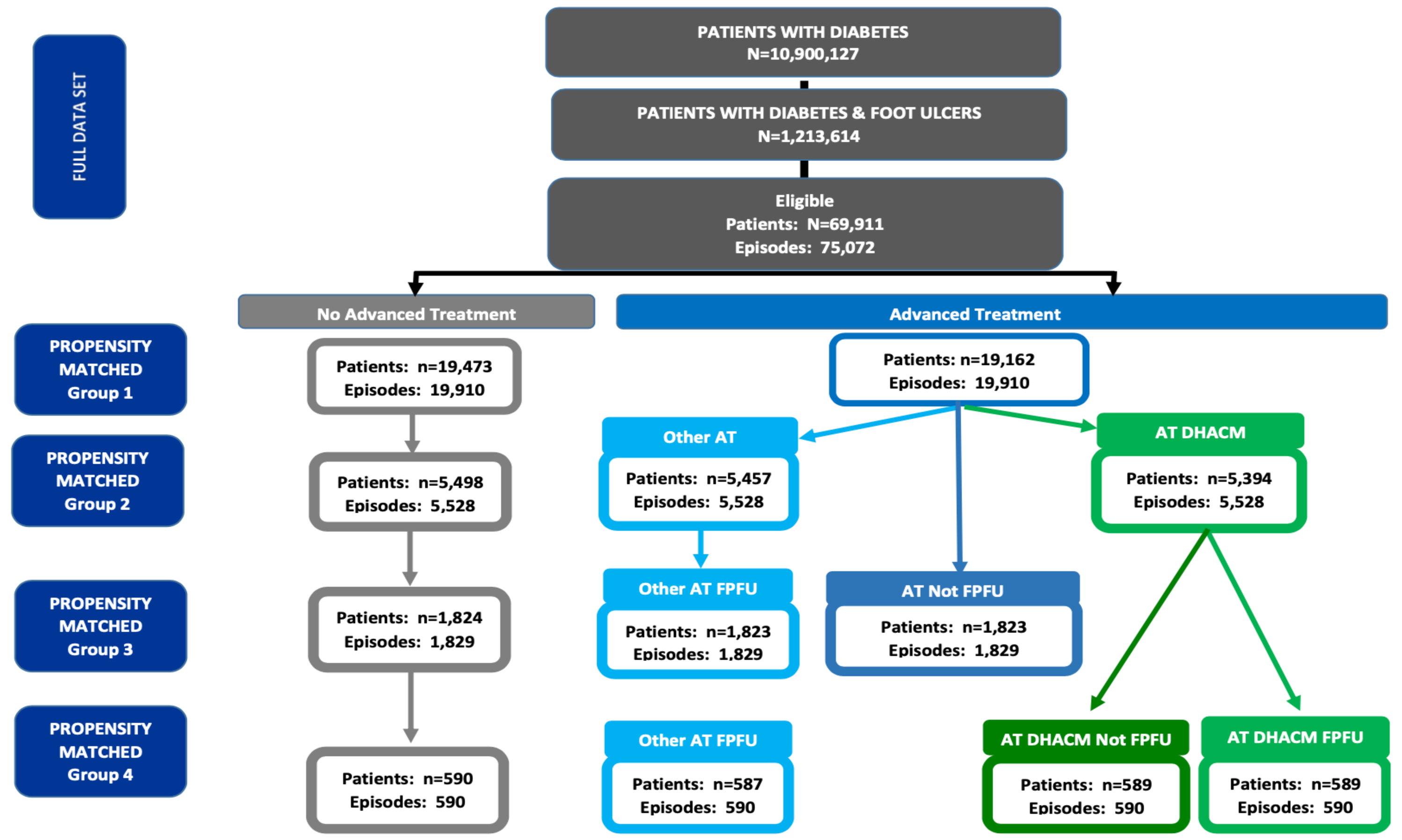
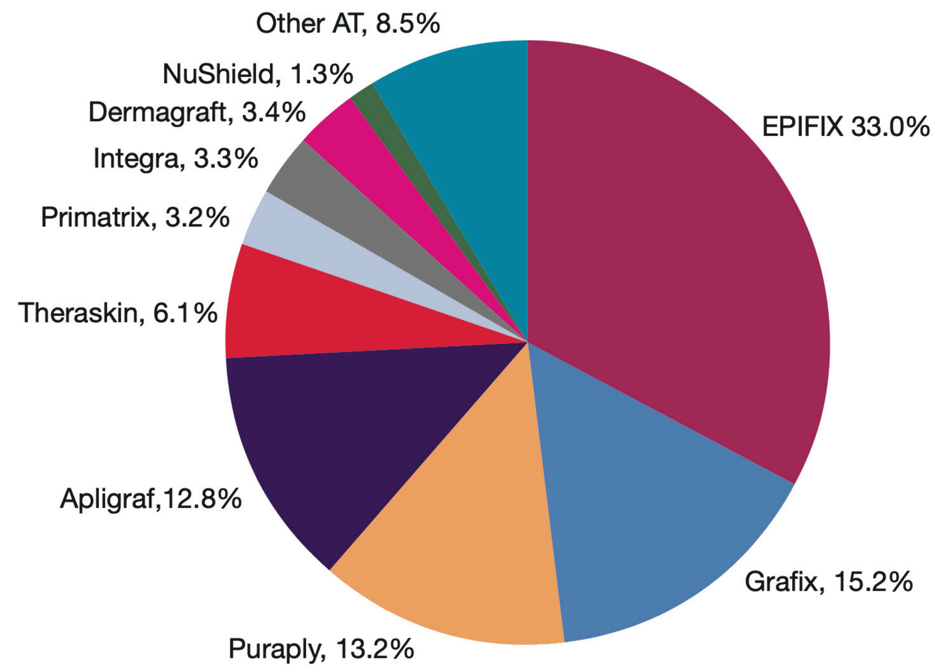


Figure 2 The percentage (%) of episodes that used an AT product are shown based on 16,735 episodes from propensity-matched group 1 derived from the Medicare data files from 2015 through 2019. Other AT=other AT brands which each had <1% usage



Episodes treated with DHACM FPFU had statistically fewer amputations and healthcare utilization. In year one, DHACM FPFU provided an additional 0.013 QALYs while saving $3,670 per patient. At a willingness-to-pay of $100,000 per QALY, the five-year Net Monetary Benefit was $9,625 (Table 2).

Table 2: Cost-Effectiveness of DHACM Treatment in LEDUs

Cost-Effectiveness Results Per Patient	Year One	Years Two to Five	Years One to Five
Cost of DHACM	$25,677	$34,315	$59,992
Cost of NAT	$29,347	$35,422	$64,769
Cost Difference	($3,670)	($1,108)	($4,777)
QALYs of DHACM	0.785	2.516	3.301
QALYs of NAT	0.772	2.481	3.252
QALY Difference	0.013	0.035	0.048
ICER ($/QALYs)	Dominant	Dominant	Dominant
NMB at $100,000 WTP Threshold	$5,004	$4,621	$9,625
Budget Impact for 1 Million Members in Year One			
Cost difference for 5,980 people at risk[8]			$21,944,742
Cost difference per 1 million members in a health plan			$21.94
Savings per member per month			$1.83

CONCLUSION

DHACM FPFU is an economically dominant strategy compared to NAT. DHACM FPFU provides better outcomes than NAT by reducing major amputations, ED visits, inpatient admissions, and readmissions. These gains are achieved at a lower cost, in years one through five and is likely to be cost-effective at any willingness-to-pay threshold. Adoption of best practices identified in this retrospective analysis is expected to generate clinically significant decreases in amputations and hospital utilization while saving money.

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*Paid speaker for MIMEDX.
Poster development supported by MIMEDX Group, Inc.

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