Value Appraisal of Neox® 1K for Complex Diabetic Foot Ulcers

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INTRODUCTION

According to the US Centers for Disease Control and Prevention (CDC), 29.1 million Americans or 9.3% of the US population had diabetes in 2014. Unfortunately, people with diabetes have a ~25% risk of developing a foot ulcer in their lifetime,[1] with an estimated annual incidence rate of 0.5-3.0%.[2-6] When the foot ulcer is non-healing, the dermal first line of defense is compromised for a prolonged period, and the patient is susceptible to tissue loss, infection, and eventual limb amputation.[7, 8] In fact, foot ulceration is a precursor to approximately 85% of the lower extremity amputations within this population.[1, 9-20]

Amputations are common in diabetic patients, with more than 73,000 non-traumatic lower extremity amputations performed in the US each year. After one major lower extremity amputation, the 5-year survival rate is estimated to be 50%[14, 15] which is worse than most malignancies.[14, 16] For amputation survivors, day-to-day function is greatly impaired; many cannot walk, with or without the use of a cane or walker. Moreover, the financial burden is cumbersome. One recent study demonstrated that excess health care costs of diabetic foot ulcers (DFU) are approximately twice that attributable to the treatment of diabetes alone, with annual incremental per-patient medical costs ranging from $11,710 to $16,883. This translates to an annual incremental payer burden ranging from $9.1 to $13.2 billion.[21] Consequently, non-healing DFUs pose a substantial clinical and economic burden on healthcare systems, with significant reductions in quality of life for those affected.

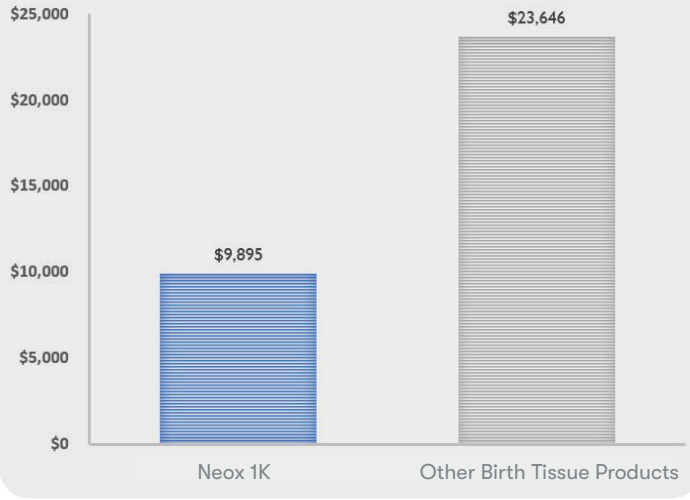
Neox 1K for DFU

To overcome the limitations with traditional treatment options, physicians have evaluated the potential of placental tissue products (amnion, chorion, umbilical cord) in its various processed forms to support the healing process in DFUs. One such product is Neox 1K, which is a cryopreserved ultra-thick human amniotic membrane product derived from umbilical cord that is used as a wound covering for dermal ulcers or defects. Multiple studies have reported wound healing rates of >78% in DFU patients who received Neox 1K[22-26] with an average time to wound closure of 13.8-16 weeks[22, 27]. Most notably, these studies were performed in patients with severe DFUs (Wagner 3 & 4) that had exposed bone/tendon/ligaments, osteomyelitis, and in some cases gangrene that are commonly contraindicated for other products.[22, 23, 25, 27] Traditionally, the healing rate in this patient population is 35% at 16 weeks using all other available therapies.[28] Hence, Neox 1K represents a potential alternative solution for the unmet medical need of complex DFUs.

Aside from the clinical outcomes, another benefit of using Neox 1K is the reduced number of applications required. Clinical evidence suggests only 1.2 to 1.7 product applications have been needed to promote wound closure despite a relatively large average wound size of 10.6-15.6 cm^2.[22, 27] This is far less than the number of applications needed for other advanced tissue products, which averages between 2.5 and 6 product applications for smaller and less severe wounds.[29-33] In terms of financial benefit, this translates to a lower overall cost ($13,751 less costly) to achieve healing with Neox 1K over a 16-week period compared to another cryopreserved human placental membrane tissue ($9,895 vs. $23,646; Figure 1).[34] The main reason for the difference in costs was the amount of tissue product (in cm^2) used, driven by less frequent applications.

Of note, these costs did not account for the higher proportion of more severe wounds in the Neox 1K patient population (Wagner 3 & 4) compared to competitor product patient population (Wagner 2), even though severe wounds are associated with higher costs (Wagner 2: $8,260 per episode, Wagner 3: $23,298 per episode, and Wagner 4/5: $52,701 per episode adjusted for inflation), and 29.4% of wounds have been shown to worsen in severity overtime.[35] Moreover, only ~4% of wounds necessitated the need for major amputation (above the ankle) after 1-year of Neox 1K exposure,[22] which thereby improves patient outlook and reduces healthcare costs. As such, when compared to other human placental tissue, Neox 1K is shown to be a more-cost effective option to improve outcomes in DFU patients.

Figure 1. Costs to Achieve Wound healing over 16 Weeks Using Different Birth Tissue Products



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