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RE: Helicoll Application for CMS Q code coverage – Important Communication

To Whom it May Concern:

Thank you so much for the allowing me the opportunity to present additional information and insight regarding the review of the application for approval of Helicoll for use in non healing diabetic foot ulcers (DFUs). Helicoll is an advanced high-purity type-I collagen-based skin substitute that is FDA-510(k)-(K040314) cleared for application on DFUs.

As is well understood DFUs affect 18.6 million people around the world every year and are associated with increased rates of amputation and death. Unfortunately, many of these foot ulcers become infected, leading to lower extremity amputations. In the United States, DFUs account for nearly one-third of the approximately $116 billion in direct costs related to diabetes[1] and precede more than 80% of all lower extremity amputations[2]. Remarkably, the 5-year mortality rate for individuals with a DFU is approximately 30% and exceeds 70% for those who undergo a major amputation. Every 20 seconds around the world a limb is amputated[3,4]. And, when compared to cancer, the 5-year mortality rate following a major (proximal to ankle) lower extremity amputation (56.6%) is second only to lung cancer (80%)[3]. These sobering statistics are a stark reminder of the challenges faced in combating this US and Global health crisis, and it is something we continue to tirelessly work with our colleagues to urgently change.

Of course, the primary goal in managing DFUs is to minimize tissue loss and preserve limb function with healing of the DFUs as expeditiously as possible.

I have served as study chair and have comprehensively reviewed the results of the attached comparative study. This study compares Helicoll to two approved Amnion grafts and highlights the success of the Helicoll skin substitute when compared to the Amnion group along with good standard of care in closing non healing diabetic foot ulcers.

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Based on the results of this study, in my opinion, I would kindly ask the committee to reconsider the application for approval. My expectation is that continued availability of this unique skin graft substitute to the Medicare population will yield promising results.. In conclusion, I would like to thank the committee for their work and consideration of my comments and would be happy to make myself available for further discussion.

Yours very truly,

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