



Title: Treatment of Venous Leg ulcers and Optimal Use of Apligraf™

Agency: AÉTMIS (formerly CETS), Agence d'évaluation des technologies et des modes d'intervention en santé

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Aim:

The Ministère de la Santé et des Services sociaux du Québec asked AÉTMIS to document the clinical and economic value of the human skin substitute known as Apligraf™ used in treating venous leg ulcers. The resulting analysis is based on the epidemiology of venous leg ulcers, on current treatment options and their efficacy, and on estimated costs.

Results and Conclusions:

Clinical issues: 1) The evaluation and diagnosis of patients should be properly performed. 2) Treatment of venous leg ulcers with compression therapy is more effective than treatment without compression. 3) Compression therapy in conjunction with Apligraf™ provides faster healing times than compression alone. 4) Compression therapy in conjunction with Apligraf™ averts more ulcer days than does compression alone.

Economic issues: In the absence of validated data, the following statements remain provisional. 1) Compression therapy simultaneously with Apligraf™ generates high costs in reducing the number of ulcer days. 2) Compression therapy plus Apligraf™ for cases that are unresponsive to initial compression therapy is less costly than compression and Apligraf™ simultaneously and offers potential savings for the healthcare system in an optimistic scenario. 3) Identifying hard-to-heal ulcers with planimetry at week 4 of initial compression therapy and subsequently adding Apligraf™ to treatment can increase savings.

Recommendations:

1) To promote: (a) continued efforts to generalize the management of leg ulcer patients according to the recommendations of advisory panels and (b) the use of compression therapy in treating venous leg ulcers. 2) To recognize, at the clinical and administrative levels, the potential role of Apligraf™ in the treatment of venous leg ulcers that are resistant to initial compression and the possible savings that could be generated. 3) To maintain rigorous policies on the use of Apligraf™ by certified physicians in hospital outpatient clinics which are, or should start, planning for specific budgets for this specialized supply. 4) To promote the dissemination of clinical and administrative protocols on the use of Apligraf™, which some hospitals have developed and implemented, so that other institutions can consider and tailor them as needed.

Methods:

Literature review (MEDLINE, Cochrane, PubMed, Current Contents, World Wide Web, surveys, institutional documents); consultation of administrative databases.

Further research required:

1) To ensure that current developments on the indications of Apligraf™ be followed up and that this report be updated following the publication of results of the multicenter pan-Canadian randomized controlled trial in the summer of 2001. 2) To initiate the research necessary to document the epidemiology of leg ulcers in Quebec and the clinical effectiveness and costs of various treatment strategies in clinical, CLSC, and home care settings.

Written by AETMIS, Canada