

Alhydran (BAP Medical BV)
hydrating creams for burns, radiodermatitis and hand-foot syndrome

Summary

BAP Medical BV has submitted a manufacturer's file on Alhydran asking for an assessment of whether Alhydran can be reimbursed as a medical aid via the insured provision 'Medical Aids' (Health Insurance Regulation (Rvz)). Alhydran is a concentrated medical gel/ointment (with no active ingredient)¹ for the treatment (focusing on repairing the transepidermal water loss (TEWL) barrier) and hydration (moisture regulation) of vulnerable skin immediately after wound closure. The medical aid can be used for the prevention and treatment of pruritus and scars due to (burn) wounds, the treatment of radiodermatitis, prevention of hand-foot syndrome, prevention of chronic wounds in cases of parchment skin after chronic wounds, and as after-care for painful and itchy surgical scars.

On the grounds of the available literature we conclude that the efficacy of Alhydran has not been researched in methodologically good clinical studies. We also carried out a broader literature search into the use of hydrating (scar) creams. We found comparative studies (level B) only in the case of treatment for radiodermatitis. The studies we found revealed considerable variations in population, products used and treatment regimes, and results were not consistent. Though it is true that a number of treatment protocols and consensus statements are available, there is no indication that this is an intervention that has been used for any length of time and for which international consensus exists regarding its efficacy. As there are no reasons for accepting a lower level of evidence (lower than randomized comparative studies, preferably blind ones), we conclude that treatment with Alhydran (or other hydrating scar creams) does not comply with established medical science and medical practice. We must add the comment that health insurers have wrongly reimbursed Alhydran from the basic insurance during a number of years.

As Alhydran and other hydrating (scar) creams do not comply with established medical science and medical practice, there is no need to examine the other package criteria. Should Alhydran (or a comparable product) comply with established medical science and medical practice in the future, CVZ will examine, where necessary, whether the product concerned should be reimbursed from the basic insurance (package principle 'necessity'), in view of the demonstrated comparability with hydrating (scar) creams generally used (for one's own account).

Alhydran (or other hydrating (scar) creams) does not comply with established medical science and medical practice and is therefore not eligible for reimbursement, either under the current definition in the Rzv (article 2.15), or under the proposed function-oriented definition.

Analysis of the GIP-databank² reveals that in the period between 2007 and 2011, Alhydran cost about three million euro. In the last year (2010), the reimbursement of Alhydran cost about one million euro.

*The original text of this **WAR-Report** of the National Health Care Institute was in Dutch. Although great care was taken in translating the text from Dutch to English, the translation may nevertheless have resulted in discrepancies. Rights may only be derived on the basis of the Dutch version of the National Health Care Institute's WAR-Report. Furthermore, the National Health Care Institute points out that only the summary of this report was translated. A proper understanding of all relevant considerations and facts would require familiarity with the Dutch version of this report, including all appendices.*

¹ By this we mean it is not a medicine.

² CIP/Health Care Insurance Board (CVZ).