Cost effectiveness of the two-compound formulation calcipotriol and betamethasone dipropionate gel in the treatment of scalp psoriasis in Scotland

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Record Status
This is a critical abstract of an economic evaluation that meets the criteria for inclusion on NHS EED. Each abstract contains a brief summary of the methods, the results and conclusions followed by a detailed critical assessment on the reliability of the study and the conclusions drawn.

CRD summary
The objective was to assess the cost-effectiveness of a two-compound formulation of calcipotriol and betamethasone dipropionate gel, used as first-, second- or third-line treatment for moderately severe scalp psoriasis. The authors concluded that the gel was cost-effective. The study was well conducted and reported, and the authors’ conclusion appears to be appropriate.

Type of economic evaluation
Cost-utility analysis

Study objective
The objective was to assess the cost-effectiveness of a two-compound formulation of calcipotriol and betamethasone dipropionate gel, used as first-, second- or third-line treatment for moderately severe scalp psoriasis.

Interventions
The intervention was the calcipotriol and betamethasone dipropionate gel (Xamiol). The comparators were standard topical treatments, including calcipotriol scalp solution, coal tar preparations, and potent or very potent topical steroids.

Twelve treatment pathways were modelled: two had the gel as a first treatment; two had it as the second option; three had it as the third option; and five were variations of usual care. The average of these five variations was used for the usual practice in Scotland.

Location/setting
Scotland/out-patient care.

Methods
Analytical approach:
A Markov model was developed to estimate the benefits and costs of the treatment options, over one year, for a cohort of adults aged 18 years or older, with moderately severe scalp psoriasis, that had not been cured by shampoos, emollients, or both. The authors stated that the perspective was that of the Scottish NHS.

Effectiveness data:
The clinical effectiveness measure was the ability of topical treatments to control disease at four weeks. Patients were classed as responders if their disease was controlled, according to Investigator Global Assessment (IGA). A systematic review of the literature from 1990 to 2008 was conducted to identify evidence on the clinical efficacy and safety of the gel, compared with commonly used topical treatments. Another review identified 10 randomised controlled trials (RCTs). The response rate was derived from head-to-head comparisons where data were available; otherwise indirect pair-wise comparisons were used. The rate for the two gel components applied separately was from a survey of around 500 Scottish general practitioners (GPs). The incidence of the most bothersome skin adverse events was estimated from all of the included studies. It was assumed that relapse occurred at the same rate per month for all topical agents.

Monetary benefit and utility valuations:
The model included 15 health states for which different utility values were derived. The utility values were from SF-36 (version two) scores, from one gel trial. These scores were transformed to SF-6D scores, using published methods. The
utilities for specific health states were assigned irrespective of which topical was used.

Measure of benefit:
The measure of benefit was the quality-adjusted life-year (QALY).

Cost data:
The direct medical costs were drugs, routine follow-up in primary care, and secondary care out-patient management. The resource use for skin adverse events was excluded. Most treatment costs were from a trial that reported the drug usage. For the non-fixed combination of calcipotriol and betamethasone dipropionate, conservative assumptions were made, due to a lack of RCT data. The cost of a GP consultation was from the Personal Social Services Research Unit. The cost of a dermatology out-patient visit was from the Scottish Information Services Division. For patients treated in the hospital day clinic, it was assumed that 10 visits were required, based on a survey of experts. Routine out-patient management was assumed to require three visits. The costs were reported in 2008 £.

Analysis of uncertainty:
A univariate sensitivity analysis was conducted to investigate the impact of varying the key clinical, utility, and cost inputs, on the results. The parameters were varied between their lower and upper 95% confidence intervals or standard deviations. Two scenario analyses were conducted, in which specific parameters were changed simultaneously.

Results
The average annual cost per patient was £272.26 for usual care; £242.54 for the gel first-line; £252.67 for the gel second-line; and £246.79 for the gel third-line. The average QALYS were 0.7819 for usual care; 0.7845 for first-line gel; 0.7844 for second-line gel; and 0.7843 for third-line gel.

Compared with usual care, the gel was dominant, as it was less costly and more effective, for first-, second-, and third-line treatment.

The gel remained dominant in most of the univariate sensitivity analyses. The results were most sensitive to the number of bottles of gel administered per course (one in the main analysis).

In the two scenarios, the results were most sensitive when the response rate for the gel was lowered, all steroid-containing topical therapies were assumed to have a relapse rate of 50%, and a higher incidence of skin adverse events was assumed for the gel. In this instance, the incremental cost-effectiveness ratio, over usual care, was about £20,000 per QALY gained for first-line gel; £16,600 per QALY gained for second-line gel; and £23,170 per QALY gained for third-line gel.

Authors' conclusions
The authors concluded that the calcipotriol and betamethasone dipropionate gel was cost-effective.

CRD commentary
Interventions:
The intervention appears to have been appropriate, and the most relevant comparator (standard practice) was included. Due to variation in usual care, an average of five options, without the gel, was used. This was reasonable given the lack of data, identified by the authors as a limitation of their study. Treatments not used in Scotland were excluded from the analysis. Each sequence of treatments was only compared with usual care, not with the other sequences.

Effectiveness/benefits:
The effectiveness estimates were clearly reported. Most were from sources that were appropriately identified by a systematic review. The poorest quality evidence was for calcipotriol and betamethasone dipropionate applied separately, which was from a survey of GPs. The inclusion criteria for the systematic review were clearly reported. An indirect comparison was conducted where head-to-head data were not available, but direct and indirect evidence could have been combined in a multiple treatment meta-analysis, which would have incorporated all the available evidence. The health state utility values and methods used to derive them were clearly reported. Discounting was not necessary.

Costs:
The costs were clearly reported and were appropriate for the perspective adopted and the setting. Appropriate sources were used for the costs, which were specific to Scotland and the UK. The price year was reported, allowing reflation exercises. Discounting was not required.

Analysis and results:
The model was clearly described, as were each of the health states. The authors stated that the short time horizon was justified, since survival and long-term outcomes were not expected to differ between the comparators, but psoriasis is a chronic relapsing-remitting condition that can affect quality of life long term. If treatment effectiveness varied over time, a lifetime horizon would have been more appropriate. Univariate sensitivity analysis and scenario analysis appropriately assessed the effects of parameter uncertainty on the results, but probabilistic sensitivity analysis could assessed the overall uncertainty. The results were robust to most analyses, supporting the authors' conclusion. The authors highlighted several limitations to their study, including the lack of quality in the comparator, utility and relapse data, and the lack of model validation.

Concluding remarks:
The study was well conducted and reported, and the authors' conclusion appears to be appropriate.

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