

# CLENIL<sup>®</sup> MODULITE<sup>®</sup> ▼

## Beclometasone dipropionate (BDP)

Prophylactic management of mild, moderate or severe asthma in adults

*Corticosteroids for the treatment of chronic asthma in adults  
and children aged 12 years and over*

*Response to the assessment report produced by the Peninsula  
Technology Assessment group and Southampton Health Technology  
Assessments Centre*

28 February 2007

Trinity-Chiesi Pharmaceuticals Ltd



Having had the opportunity to review the assessment report, *ICS and LABAs for the treatment of chronic asthma in adults and children aged 12 years and over: Systematic review and economic analysis*, carried out on behalf of NICE, we would like to draw the Appraisal Committee's attention to the following points regarding Clenil<sup>®</sup> Modulite<sup>®</sup> (beclometasone dipropionate, Trinity-Chiesi Pharmaceuticals Ltd, UK).

It is inappropriate to infer that consideration of the service cost of switching from chlorofluorocarbon (CFC)-containing products to CFC-free BDP products is outside of the scope of the present review (page 376). For a switch to the main alternative CFC-free BDP product (Qvar<sup>®</sup>), there will be costs associated with the need for therapeutic reviews, retitration and monitoring response. The use of Clenil<sup>®</sup> Modulite<sup>®</sup> rather than Qvar<sup>®</sup> is expected to save £30.74 per patient during the first year after switching to CFC-free BDP. Although short-term, this £30.74 is a real service cost that is avoided with Clenil<sup>®</sup> Modulite<sup>®</sup> and should as such be considered within the scope. When comparing inhaled corticosteroid (ICS) products, it is inappropriate to consider all BDP products together in a 'one-cost' category.

Indeed, in section 6.5.3.1 (pages 387–393), there is recognition of differences in drug prices within ICS drug classes (see Figures 25–28), which is somewhat incongruous with the earlier statement that comparisons between BDP drugs are outside the scope of the review (page 376).

In Figure 26 (page 390), the assessment report states that the cheapest BDP product based on the annual cost of taking 400 µg BDP-CFC equivalent per day, excluding CFC-propelled products, is Clenil<sup>®</sup> Modulite<sup>®</sup>. However, in Figure 28 (page 393), the report claims that the cheapest BDP product based on the annual cost of taking 800 µg BDP-CFC equivalent per day, excluding CFC-propelled products, is Qvar<sup>®</sup>. It is difficult to understand how Qvar<sup>®</sup> can be considered cheaper than Clenil<sup>®</sup> Modulite<sup>®</sup> at this higher dose, as Table 56 on page 377 clearly shows Clenil<sup>®</sup> Modulite<sup>®</sup> to be of lower cost at each dose. We believe that there is an error in Figure 28 – it should state that Clenil<sup>®</sup> Modulite<sup>®</sup> is the cheapest BDP product.

In contrast to the rest of the report, section 7 – the chapter on factors relevant to the NHS and other parties – is very brief. There is no mention in section 7.1 of the service impact, in terms of therapeutic reviews and monitoring, associated with switching from CFC-containing to CFC-free BDP products over the next 18 months. Although short-term, this will affect a large number of patients whose asthma is controlled by BDP alone, so the impact of this switch should be properly assessed.

Overall, although the scope of the report is aimed at inter- and intra-class comparisons, there are important product and service impact differences within the BDP group that need to be given more attention.

Dear Alana

Thank you for sending us the assessment reports on corticosteroids for the treatment of chronic asthma.

You will find attached the response of Trinity-Chiesi Pharmaceuticals Ltd regarding Clenil® Modulite®. There are two response documents – one for adults and children aged 12 years and over, and one for children under the age of 12 years.

On behalf of Trinity-Chiesi, we would also like to point out an inaccuracy regarding Pulvinal®. Page 14 of the adults' report and page 16 of the children's report should state that Pulvinal is a **dry powder inhaler**.

Please do not hesitate to contact me, or my colleague, if you have any questions at all.

Kind regards

Delivered via MessageLabs

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