

CLENIL[®] MODULITE[®] ▼

Beclometasone dipropionate (BDP)

Prophylactic management of mild, moderate or severe asthma in children

*Corticosteroids for the treatment of chronic asthma in
children under the age of 12 years*

*A Health Technology Appraisal for the
National Institute for Health and Clinical Excellence*

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Trinity-Chiesi Pharmaceuticals Ltd



1. EXECUTIVE SUMMARY

- Asthma is a common and potentially fatal condition that is estimated to affect almost one in three British children.
- Inhaled corticosteroids (ICSs) are a cornerstone of asthma management, as the first-choice preventer treatment at Step 2 of the current British Thoracic Society (BTS)/Scottish Intercollegiate Guidelines Network (SIGN) guideline.
- Beclometasone dipropionate (BDP) has been in clinical use for longer than any other ICS, and is the most widely used ICS in the UK. This extensive clinical experience is particularly important when prescribing long-term therapy for children.
- Pressurised metered-dose inhalers (pMDIs) are the main inhaler devices used for asthma therapy, with equivalent effectiveness to alternative inhaler devices. However, standard pMDIs contain chlorofluorocarbons (CFCs), and must be withdrawn in line with the Montreal Protocol.
- Clenil[®] Modulite[®] is currently the only non-CFC-containing pMDI formulation of BDP that is available for children younger than 12 years in the UK. In addition, Clenil[®] Modulite[®] is the first non-CFC-containing pMDI formulation of BDP that is directly equivalent to existing CFC-containing BDP pMDIs.
- Phase III studies have demonstrated that Clenil[®] Modulite[®] is directly equivalent to a standard CFC-containing pMDI formulation of BDP that is widely used in the UK (Becotide[®]). Safety studies have confirmed that Clenil[®] Modulite[®] has no increased effect on the hypothalamo–pituitary–adrenal (HPA) axis compared with a standard BDP pMDI formulation.
- Direct drug cost savings alone (without taking account of any reduced resource costs for therapeutic review) would be around £16,000–£92,000 per annum for a 300,000-population primary care organisation (PCO), using Clenil[®] Modulite[®] instead of the two other non-CFC-containing BDP inhalers licensed for paediatric use in the UK (Asmabec[®] Clickhaler[®] and Becodisks[®] Diskhaler[®]).

- Clenil[®] Modulite[®] offers the only simple and cost-effective alternative to dry powder inhalers (DPIs) for children aged up to 11 years in the transition period from CFC-containing to non-CFC-containing BDP inhaler devices.