Please note that this document has not been updated for the 2026-27 incentive scheme. Standard Operating Procedures (SOPs) for medicines optimisation switches/reviews, along with other supporting materials, were originally developed for use by Medicines Optimisation Team staff within NHS South Yorkshire Integrated Care Board (ICB). Other organisations or groups choosing to use this resource does so at their own risk and NHS SY ICB accepts no liability for its use or application.

Clenil Modulite and Generic Beclometasone pMDI to Soprobec Inhaler

Bottom line: Soprobec is a generic CFC-free beclometasone dipropionate launched in the UK as an alternative to Clenil® Modulite. Soprobec offers the same range of inhaler strengths as Clenil® Modulite® in an equivalent inhaler.

Launch Date: **QIPP 2025/2026**

Practices: **All**

Pharmacists and pharmacy technicians undertaking this action sheet should work within their clinical competence. Where appropriate please read in conjunction with appropriate referenced documents, the BNF and the relevant summary of product characteristics. If you are unsure, please speak to your line manager or one of the clinical leads '

Background / Evidence base

Soprobec is a generic CFC-free beclometasone dipropionate launched in the UK as an alternative to Clenil® Modulite®. Soprobec provides dosing equivalence to Clenil® Modulite®, at a lower cost. Soprobec offers the same range of inhaler strengths as Clenil® Modulite® in an equivalent inhaler device.

Soprobec is an inhaled corticosteroid indicated for the maintenance treatment of asthma when the use of a pressurised metered dose inhaler is appropriate. The licence states Volumatic™ spacer device is required in patients 15 years of age and under, and all patients requiring daily doses of 1000 mcg and over. This is the same as the licensing for Clenil® Modulite® therefore this should not impact on any switches where patients are already using aerochamber devices as neither are approved for use with aerochamber devices. NB ideally all patient using a pMDI inhaler should use a spacer device to help improve drug delivery.

Formulation studies confirmed the pharmaceutical equivalence of Soprobec to the reference product for 50, 100, 200, and 250 mcg per actuation.

Cost Savings

	50 mcg	**100mcg**	**200mcg**	**250mcg**
Clenil	£3.70	£7.42	£16.17	£16.29
Soprobec	£2.78	£5.57	£12.13	£12.22
Saving per inhaler	**£0.98**	**£1.85**	**£4.04**	**£4.07**

Exclusions

- **Age under 18** – Children's respiratory specialists have previously stated they would like all children to be seen face to face when prescribing a different inhaler since the inhaler colours are different. They are happy for Soprobec to be used in children and understand that new prescribing will be for Soprobec and that children may be seen and switched face to face by practices.
- **Patients with COPD only and no asthma**
- **For all ages if previously tried Soprobec and switched back to Clenil.**

Caution

- **Where a dose counter is essential** to ensure compliance and appropriate inhaler use – Soprobec does not have a dose counter. For many people dose counters are essential to ensure compliance and to indicate to them where their inhalers are due to be replaced. Since beclometasone is a regular dosing regime patients could mark on the device or box the date first used and or the date it will run out. Each inhaler contains 200 doses therefore 1 inhaler at a dose of 1 puff BD would last 100 days. There are also counter apps available for mobile devices which can be utilised to keep track of doses.

Differences in Device

The Soprobec inhaler range looks like this:

Image source Sporobec.co.uk

The Clenil Modulite inhaler range looks like this:

Image source chiesi.uk.com

As you can see there is a difference in the colour of the inhalers. Therefore, the wording of your messages to patients should reflect this. Please see "Communication to Patients" for further information.

Please be aware Clenil has a dose counter however Soprobec does not we should have a **low tolerance to switching back** should a dose counter be important to the patient. (see cautions for further information)

As previously mentioned, both Clenil and Soprobec are compatible with Volumatic spacer. This should not impact on any switches where patients are already using aerochamber devices as neither are approved for use with aerochamber devices.

Other Clinical Effectiveness Considerations

Position of pMDI's and green agenda

Please explain that this is a like for like device switch. The inhalers are very similar so the patient shouldn't notice a difference (other than colour). pMDI to DPI switches should only be done face to face and they must be trained on how to use the new device.

New BTS/NICE/SIGN Guidance Nov 2024

The new BTS/NICE/SIGN Asthma Guideline published in 2024 made 2 bold statements. Firstly, that no patient with asthma should be managed with SABA (short acting beta agonist) monotherapy and secondly, that for adults and adolescents 12+ the only recommended treatment regime is a pathway using ICS/formoterol combination inhaler as with AIR (anti-inflammatory reliever therapy) or MART (maintenance and reliever therapy). The guidance recommends that for patients well controlled on alternative treatment regimes should be allowed to continue however if they are not well controlled, we should consider changing them to an appropriate strength MART regime. (Anyone on SABA monotherapy should be offered AIR). Uncontrolled asthma is defined as any exacerbation requiring OCS (oral corticosteroids), frequent symptoms such as needing a reliever inhaler 3+ times a week or waking up at night one or more times a week due to asthma symptoms. This should be considered when carrying out this piece of work. See https://www.nice.org.uk/guidance/ng245/resources/algorithm-c-pharmacological-management-of-asthma-in-people-aged-12-years-and-over-bts-nice-sign-pdf-13556516367 for further information.

To assist the practice and increase the clinical benefit of this switch work to them and the patients, it is recommended that we help them identify uncontrolled asthma patients who they could prioritise for a face-to-face review and potential switch to AIR or MART (and or DPI) where appropriate by checking the patients notes for the following and referring where appropriate:

Asthma

- No asthma review in 12 months
- Poor asthma control shown by ACT score < 15 and or >6 SABA in 12 months
- Documented symptoms suggesting poor asthma control (reliever inhaler needed 3+ times a week or waking up at night one or more times a week due to asthma symptoms)
- OCS course for asthma exacerbation in the last 12 months
- Inadequate inhaler technique documented in previous 12 months
- No assessment of inhaler technique documented in previous 12 months

NB anyone using 3+ SABA in 12 months is potentially over reliant/uncontrolled – 6+ has been chosen so as to identify the highest SABA users.

COPD

Clenil/Soprobec are not licensed for COPD therefore any patient with COPD could benefit from a review of therapy in line with local guidelines where available. NB it is not unheard of for specialists to put COPD patients with coexisting asthma onto a dual bronchodilator + separate ICS) Please do not switch patients with COPD and no history of asthma and highlight any patients to the practice for review of their existing medication in line with local guidelines.

Communication with patients

Due to patient and community pharmacy feedback, it is recommended that the patient receives a written communication which informs them of the change of inhaler and specifically the change of colour of inhaler. An AccuRx message or letter to patients may be the most appropriate method of communication for this switch and **some additional leaflets have been produced to support switching via AccuRx or letter.** NB these are separate document.

Sample information for dosage line:

Inhale ONE puff TWICE daily (This replaces Clenil inhaler and contains the same medication)

Action required	**By**
1. Search for patients using Clenil Modulite 50,100, 200 and 250mcg strengths as well as those using generic beclometasone CFC free pMDI inhalers 50,100,200 and 250mcg strengths. Exclude under 18's, patients who have previously tried Soprobec and switched back to Clenil and patients with COPD only and no asthma.	Pharmacist/Technician
2. Discuss and gain agreement with the prescribing lead G.P. Please inform line manager if any major barriers to carrying out the work.	Pharmacist/Technician
3. Liaise with the community pharmacy where appropriate.	Pharmacist/Technician
4. Carry out agreed switches/actions and communicate to the patient in the agreed manner	Pharmacist/Technician
5. Where agreed/requested by the practice please provide a list of patients meeting the criteria for review as documented in the action sheet/SOP (see data collection sheet)	Pharmacist/Technician

References:

Medicine and Healthcare products Regulatory Agency (MHRA). Public assessment report. Soprobec 50 micrograms per actuation pressurised inhalation solution; Soprobec 100 micrograms per actuation pressurised inhalation solution; Soprobec 200 micrograms per actuation pressurised inhalation solution; Soprobec 250 micrograms per actuation pressurised inhalation solution (Beclometasone dipropionate). https://mhraproductsprod.blob.core.windows.net/docs-20200302/3bc836d25349185931b189bf3ba25c395c23447b

SPC Clenil Modulite
SPC Soprobec Inhaler

Appendices

- Appendix 1 Letter to patient
- Appendix 2 Care home communication form

Appendix 1 Sample letter to patient

Your doctor has agreed a change to your prescription medication

Prescribing at the practice is regularly reviewed to make sure patients are receiving the most suitable and cost-effective medication.

At the moment you take Clenil Modulite / beclometasone CFC free pMDI [strength] [form] - [dose]
This has been changed to another brand of the same medication called **Soprobec [strength] [form] - [dose]**

These inhalers contain the same medication so work in the same way and are equally effective but Soprobec is available at a lower cost to the NHS. This means that the savings made by prescribing this instead of Clenil Modulite / beclometasone CFC free pMDI can then be used to support and improve other NHS services.

Please note:

- The change will not affect the way your condition is managed; you will continue to be monitored by your doctor as before.
- Your next repeat prescription will be changed to **Soprobec.** Please continue to use your current supply of Clenil Modulite / beclometasone CFC free pMDI as prescribed by your doctor until the pack is finished and you collect your new prescription.
- The new **Soprobec** should be used in exactly the same way as your old brand of medication. **Do not use both together.**
- The attached leaflet provides further information including any change of colour to your inhaler.
- Please read the patient information leaflet provided with the new medication.
- This letter only refers to the change to **Soprobec.** All your other medication should be taken as prescribed by your GP.

I hope you are happy about the reasons for this change. If you have any concerns or notice any changes in your condition please contact the surgery.

Yours sincerely,

XXXXXXXXXX
Pharmacy Technician / Clinical Pharmacist
On behalf of the doctors at XXXXXXXXXXXX

Appendix 2

Practice logo
Care home name …….
Your doctor has agreed a change to your resident's prescription medication Date……

Resident name / NHS number	D.O.B	Current prescribed item / dose/formulation / strength	Changed to	State if this is ; 1. Medication changed to brand 2. Medication changed to generic 3. Cost effective alternative 4. Any other reason e.g. out of stock	Any precautionary message

The change will not affect the way the condition is managed and will continue to be monitored by the doctor as before
Please inform your dispensing pharmacy of the change in order to remove the original item from the MAR chart to prevent duplication
Additional message

Appendix 3

Sample right-hand side note messages Clenil to Soprobec:

"Please note your Clenil 50 inhaler has been changed to the brand Soprobec 50. This inhaler works in the same way as Clenil and contains the same medication (beclometasone dipropionate) at the same strength. The new device is still cream with a brown cap. You should notice no difference in the management of your condition. You may notice the new inhaler does not have a dose counter. If this is important to you, please get in touch.
Dear Community pharmacist please inform patient of the above change, Thank you."

"Please note your Clenil 100 inhaler has been changed to the brand Soprobec 100. This inhaler works in the same way as Clenil and contains the same medication (beclometasone dipropionate) at the same strength. The new device is a different colour it is grey with a light pink cap. You should notice no difference in the management of your condition. You may notice the new inhaler does not have a dose counter. If this is important to you, please get in touch.

Dear Community pharmacist please inform patient of the above change, Thank you."

"Please note your Clenil 200 inhaler has been changed to the brand Soprobec 200. This inhaler works in the same way as Clenil and contains the same medication (beclometasone dipropionate) at the same strength. The new device is a different colour it is light pink with a red/brown cap. You should notice no difference in the management of your condition. You may notice the new inhaler does not have a dose counter. If this is important to you, please get in touch.
Dear Community pharmacist please inform patient of the above change, Thank you."

"Please note your Clenil 250 inhaler has been changed to the brand Soprobec 250. This inhaler works in the same way as Clenil and contains the same medication (beclometasone dipropionate) at the same strength. The new device is a different colour it is red/brown with a light grey cap. You should notice no difference in the management of your condition. You may notice the new inhaler does not have a dose counter. If this is important to you, please get in touch with the practice.
Dear Community pharmacist please inform patient of the above change, Thank you."

Sample right-hand side note messages Generic beclometasone to Soprobec:

"Please note your Beclometasone 50 inhaler is now prescribed as the brand Soprobec 50. This inhaler works in the same way and contains the same medication (beclometasone dipropionate) at the same strength. You may already be receiving Soprobec from the pharmacy. The new device is still cream with a brown cap. You should notice no difference in the management of your condition. You may notice the new inhaler does not have a dose counter. If this is important to you, please get in touch with the practice.
Dear Community pharmacist please inform patient of the above change, Thank you."

Please note your Beclometasone 100 inhaler is now prescribed as the brand Soprobec 100. This inhaler works in the same way and contains the same medication (beclometasone dipropionate) at the same strength. You may already be receiving Soprobec from the pharmacy. The new device may be a

different colour it is grey with a light pink cap. You should notice no difference in the management of your condition. You may notice the new inhaler does not have a dose counter. If this is important to you, please get in touch with the practice.
Dear Community pharmacist please inform patient of the above change, Thank you."

Please note your Beclometasone 200 inhaler is now prescribed as the brand Soprobec 200. This inhaler works in the same way and contains the same medication (beclometasone dipropionate) at the same strength. You may already be receiving Soprobec from the pharmacy. The new device may be a different colour it is light pink with a red/brown cap. You should notice no difference in the management of your condition. You may notice the new inhaler does not have a dose counter. If this is important to you, please get in touch with the practice.
Dear Community pharmacist please inform patient of the above change, Thank you."

Please note your Beclometasone 250 inhaler is now prescribed as the brand Soprobec 250. This inhaler works in the same way and contains the same medication (beclometasone dipropionate) at the same strength. You may already be receiving Soprobec from the pharmacy. The new device may be a different colour it is red/brown with a light grey cap. You should notice no difference in the management of your condition. You may notice the new inhaler does not have a dose counter. If this is important to you, please get in touch with the practice.
Dear Community pharmacist please inform patient of the above change, Thank you."