

# Asthma

This bulletin discusses the pharmacological management of chronic asthma, with a focus on supporting the implementation of National Institute for Health and Care Excellence (NICE) guidance. It considers some of the differences between NICE and British Thoracic Society (BTS)/Scottish Intercollegiate Guidelines Network (SIGN) asthma guidance and looks at prescribing considerations that affect treatment. Other key issues in asthma management, such as review, treatment stepdown, adherence and safety are also considered.

A range of support materials to facilitate medicines optimisation in asthma are available at <u>https://www.prescqipp.info/our-resources/bulletins/bulletin-251-asthma/, including:</u>

- Pathway documents that can be adapted for local use
- Spreadsheet of available asthma inhalers, including costs
- Asthma treatment pathway costing tool
- Searches to support identifying people at higher risk (based on the National Review of Asthma Deaths (NRAD) report)
- NHS branded inhaler technique videos and leaflets

The focus of the bulletin and support resources is pharmacological treatment, so non-pharmacological treatment and diagnosis are not considered here.

Other sources of information about asthma, inhalers and spacers include <u>www.rightbreathe.com</u> and <u>www.asthma.org.uk</u>.

#### Recommendations

- Agree local guidance for the management of asthma in consultation with local experts. Consider guidance from NICE and joint guidance from BTS and SIGN.<sup>1-3</sup> Pathway documents (based on NICE guidance) that can be adapted for local use are available at <a href="https://www.prescqipp.info/our-resources/bulletins/bulletin-251-asthma/">https://www.prescqipp.info/our-resources/bulletins/bulletin-251-asthma/</a>.
- Local decision-makers must consider where to position treatments, such as leukotriene receptor antagonists (LTRA) and maintenance and reliever therapy (MART) with inhaled corticosteroid (ICS) + long-acting beta<sub>2</sub>agonists (LABA), for which there are differing recommendations from NICE and BTS/SIGN.
- Commissioners should ensure that it is clear where adolescents fit into local asthma pathways.
- Practices should have robust systems in place to ensure that people with asthma are reviewed appropriately. As well as routine review, this also includes review of people that may be overtreated or undertreated.
- Integrate the recommendations of the National Review of Asthma Deaths (NRAD) into the routine monitoring of asthma prescribing in practices and urgently follow up those at greatest risk of adverse outcomes (see 'Safety' section, page 13). This includes people that over-use Short-Acting inhaled Beta, Agonists (SABA) inhalers or under-use preventer medications (or both).<sup>4</sup>

### Recommendations

- Consider decreasing maintenance therapy once a person's asthma has been controlled with their current maintenance therapy for at least three months.<sup>1,2</sup>
- Ensure that every person with asthma has an up to date personalised asthma action plan (PAAP).<sup>1-3</sup>
   Asthma action plans for adults and children can be found on the Asthma UK website
   (www.asthma.org.uk) and are available in English and Welsh languages.
- Ensure that when a person is first prescribed an inhaler, they are shown how to use it and that they can demonstrate they are able to use it. Inhaler technique should be observed and advised upon regularly, including when the inhaler device is changed and when there is deterioration in asthma control.<sup>1-3</sup> NHS branded inhaler technique videos and leaflets are available as support resources at https://www.prescqipp.info/our-resources/webkits/respiratory-care/
- Make use of community pharmacy services that can support people in getting the most from their asthma medication. Information about the Community Pharmacy New Medicine Service (NMS) and Medicine Use Reviews (MURs)(decommissioned from the end of 20/21) for healthcare professionals can be found in attachment 1, and a Patient Information Leaflet on the NMS can be found in attachment 2. The Asthma UK website contains information entitled 'Make the most of your pharmacist', which also discusses these services, and is available from Asthma UK at: <a href="https://www.asthma.org.uk/advice/manage-your-asthma/pharmacist/">https://www.asthma.org.uk/advice/manage-your-asthma/pharmacist/</a>
- When making a formulary choice, or a choice about an individual's treatment, aim to minimise the range of inhaler types the patient needs to master, in order to reduce the risk of confusion or errors in use.<sup>3</sup> Where possible prescribe the same type of inhaler device to deliver preventer and reliever treatments.
- When making a formulary choice, consider the ability to step down treatment. Depending on how MART is positioned in local guidance, it may be important to consider how easily people can move from low dose ICS + LABA as a fixed-dose regimen to a MART regimen.
- Prescribers should be aware of environmental issues relating to inhaler devices and be able to discuss them as part of shared decision making. Dry powder inhalers (DPIs) have a lower carbon footprint than pressurised metered dose inhalers (pMDIs) and should continue to be included as an option (for appropriate patients) in local formularies.<sup>5</sup>
- Local guidance should support prescribers in selecting the least expensive treatment option that is appropriate and acceptable to the individual. An asthma treatment pathway costing tool is available at: <u>https://pdata.uk/#/views/ChronicAsthmaTreatmentPathwayCostingTool/IntroNotes?:iid=1</u> to enable commissioners to estimate the financial impact of different asthma pathways and formulary choices they are considering.
- People should not have their treatment changed purely to follow NICE recommendations where they represent a change from traditional clinical practice guidance.<sup>2</sup> If treatment changes are clinically indicated (e.g. step-down/up treatment) people may be treated in line with a new locallyagreed pathway, where this is available. Examples of transitions from a BTS/SIGN-based asthma pharmacological treatment pathway to a NICE-based pathway are provided as a support resource in attachment 3.
- When using ICS, use of other corticosteroid therapy (including topical) or concurrent use of drugs which inhibit corticosteroid metabolism should be taken into account when assessing systemic risk.<sup>6</sup> Ensure steroid cards are issued to appropriate people, such as those on a high-dose ICS.<sup>7</sup>
- Ensure that preventer inhalers with extra-fine particle formulations (e.g. Qvar®, Fostair®) are prescribed at doses that reflect their greater potency compared to non-extra-fine particle formulations.<sup>6</sup>

### Recommendations

- Ensure that people using a pMDI also receive a spacer where appropriate. Provide information and training on how to use and care for the spacer device <a href="https://www.prescqipp.info/our-resources/bulletins/bulletin-221-respiratory-spacer-videos/">https://www.prescqipp.info/our-resources/</a> bulletins/bulletin-221-respiratory-spacer-videos/
- Prescribe inhalers by brand and device to ensure that the person receives the intended inhaler that they are familiar with and have been trained to use properly.<sup>3</sup>
- Use specific instructions for prescriptions and pharmacy labels for inhalers. Avoid non-specific instructions, such as 'as directed'. As well as being documented in the patient record and the PAAP, it should be clear from the instructions on the prescription for a combination inhaler what type of regimen the person is prescribed (i.e. fixed-dose or MART).
- Advise people to return old inhalers to a pharmacy. Some pharmacies offer an inhaler recycling service. All pharmacies can dispose of pMDI canisters (which still contain greenhouse gas propellants) in an environmentally safe way.<sup>5</sup>

### Background

Asthma is a chronic condition associated with airway inflammation and hyper-responsiveness.<sup>8</sup> It is the most commonly diagnosed long-term medical condition in the UK,<sup>1</sup> and much of its management takes place in primary care.<sup>9</sup> Asthma treatment aims to control the symptoms of the condition, which can vary over time.<sup>8</sup> People with poorly controlled asthma are at greater risk of an acute exacerbation (an asthma attack), which can be life-threatening.<sup>4</sup>

In the UK, 5.4 million people are currently receiving treatment for asthma: 1.1 million children (1 in 11) and 4.3 million adults (1 in 12).<sup>10</sup> National public sector spending for asthma has been estimated at approximately £1.1 billion each year, with the majority of costs (74%) resulting from the provision of primary care services (60% prescribing, 14% consultations).<sup>11</sup>

Medicines optimisation in asthma focuses on regular clinical review, tackling overtreatment and proactively identifying people whose asthma is not well controlled (particularly those at highest risk of adverse outcomes). Local guidance should support prescribers in selecting the least expensive treatment option that is appropriate to the individual's needs.

### National guidance

Joint guidance from BTS/SIGN on the diagnosis and management of asthma has been available for several years. This guidance has been updated regularly, most recently in July 2019.<sup>3</sup>

In 2013 it was decided that NICE would produce a guideline for diagnosis and monitoring of asthma, and later for the management of chronic asthma. One of the drivers for this was the desire to include cost effectiveness analyses, which are not considered within the BTS/SIGN guideline.<sup>9</sup> In November 2017, NICE published NG80 'Asthma: diagnosis, monitoring and chronic asthma management'.<sup>2</sup>

An international asthma guideline is produced by the Global Initiative for Asthma (GINA).<sup>12</sup> This is referenced in both the BTS/SIGN and NICE asthma guidelines.<sup>1,3</sup> The GINA asthma guidelines were most recently updated in 2019.<sup>12</sup>

The Primary Care Respiratory Society has produced consensus guidelines, Asthma Guidelines in Practice: a PCRS consensus. The aim of their guidelines is to provide clarity on aspects of diagnosis, management and monitoring of asthma that are uncertain due to differences between the two current UK national guidelines.<sup>13</sup>

There is considerable overlap in the scope of the NICE and BTS/SIGN asthma guidelines. Both consider diagnosis, monitoring and chronic asthma treatment. However, the BTS/SIGN guideline remit is broader, and it also considers the management of acute asthma, difficult asthma, and special populations such as pregnant women and adolescents.<sup>3</sup> Where the scopes overlap, both sets of guidelines considered broadly the same evidence-base, resulting, in the most part, in similar recommendations. There are, however, some notable differences resulting from methodological differences in how the recommendations are produced.<sup>14</sup> Future UK chronic asthma guidelines are expected to be produced jointly by NICE, BTS and SIGN,<sup>15</sup> which should eliminate such discrepancies.

The pharmacological treatment options recommended by NICE are discussed below, with a focus on areas where NICE and BTS/SIGN guidance differs. A support resource that considers these differences in more detail is available in attachment 11 (see 'Background to the differences between chronic asthma treatment guidelines from BTS/SIGN and NICE').

#### **Initial treatment**

NICE include SABA alone as a potential initial treatment in their asthma treatment algorithms.<sup>1</sup> This could be viewed as conflicting with the findings of NRAD (see 'Safety' section), and with the approach adopted by BTS/SIGN, who recommend initiation of treatment with a low dose ICS.<sup>3</sup> NICE included the option of SABA alone as no evidence was identified to justify starting all people with asthma on an ICS preventer.<sup>1</sup>

It should be emphasised that NICE only include SABA alone as an option for those with short-lived, infrequent wheeze and normal lung function (or in children less than five years, for symptoms that do not indicate the need for maintenance therapy at presentation). Anyone with symptoms that indicate the need for maintenance therapy at presentation should move directly to treatment with ICS.<sup>1</sup>

Over-use of SABA inhalers and under-use of preventer medications have been highlighted as key contributors to asthma-related deaths in the NRAD Report.<sup>4</sup>

The use of SABA inhalers should be closely monitored (see 'Safety' section).

#### Place of leukotriene receptor antagonists (LTRA)

NICE and BTS/SIGN differ in their choice of first-line add on treatment to low dose ICS, for adults and children five years and older. NICE recommend a trial of an LTRA before initiating a LABA,<sup>1</sup> whereas BTS/SIGN advocate the addition of a LABA first.<sup>3</sup>

Both BTS/SIGN and NICE found LABA to be modestly superior to LTRA as adjunctive treatment, primarily due to a reduction in severe exacerbations.<sup>1,3</sup> However, in NICE's analysis the difference between ICS + LABA and ICS + LTRA for severe exacerbations did not breach the pre-determined minimally important difference relative risk ratio of 1:1 (i.e. no clinically important effect was detected).<sup>1</sup> Furthermore, NICE's cost-effectiveness analysis identified a trial of ICS + LTRA to be the more cost-effective treatment option (compared with ICS + LABA) for individuals who remain uncontrolled on low dose ICS alone.<sup>1</sup>

It has been argued that the addition of an LTRA (which requires an oral medication to be taken every evening) could adversely affect adherence, compared with adding a LABA (where only the brand name of the inhaler need change). Also, ICS + LTRA incurs two prescription charges, compared with a single charge for a combination inhaler.<sup>14</sup> Factors such as concordance and individual preference should be part of the discussion when considering a person's treatment. People that pay for their prescriptions should be advised of the availability of pre-payment certificates, which can essentially cap the cost of prescriptions to 12 charges per year. Information about who might benefit from a pre-payment certificate, and how to obtain one can be found on the NHS website at: <a href="https://www.nhs.uk/using-the-nhs/help-with-health-costs/save-money-with-a-prescription-prepayment-certificate-ppc/">https://www.nhs.uk/using-the-nhs/help-with-health-costs/save-money-with-a-prescription-prepayment-certificate-ppc/</a>

The Primary Care Respiratory Society (PCRS) asthma guidelines support NICE's recommendation to try an LTRA as first-line add on therapy to ICS (unless there is good reason to the contrary), noting that cost is a key consideration for the NHS.<sup>13</sup>

NICE emphasise two important points in their guidance:

- After four to eight weeks, the response to LTRA should be assessed. The decision to continue or stop the LTRA should be based on a discussion with the person, taking into account the degree of response to treatment.
- The recommendation, which represents a change from traditional clinical practice, applies to people with newly diagnosed asthma or asthma that is uncontrolled on their current treatment. People whose asthma is well controlled on their current treatment should not have their treatment changed purely to follow this guidance.<sup>2</sup>

For children aged five to 16, NICE again recommend an LTRA as first-line add on treatment to low dose ICS. However, the recommendation is worded as 'consider' because of a much weaker evidence base in this age group.<sup>1</sup>

No evidence was included in the NICE review for LTRAs in the under five age group; recommendations were based on the clinical experience of the guideline committee. NICE recommend considering the addition of an LTRA to paediatric low dose ICS in children under five years whose suspected asthma is uncontrolled on ICS alone. A specialist opinion should be sought before progressing beyond an LTRA in this age group.<sup>1</sup>

#### Place of maintenance and reliever therapy (MART)

MART involves the use of combined ICS + fast-acting LABA in a single inhaler, which is used for both daily maintenance therapy and 'as required' symptomatic relief. MART is only feasible with ICS + LABA combinations in which the LABA has a fast-acting component, such as formoterol, and not all formoterol-containing combination inhalers are licensed for this use<sup>2</sup> (see attachment 4 for a summary of products licensed for MART). MART features in both the BTS/SIGN and NICE guidance on asthma management, although it is placed more prominently in the NICE guideline.<sup>1,3</sup>

NICE guidance recommends offering MART (with a low maintenance ICS dose) if asthma is uncontrolled in adults ( $\geq$ 17 years) on a low dose of ICS and a LABA, with or without an LTRA. Rather than being an option to consider in some people, NICE position MART as a distinct treatment step to be taken before progressing to a higher dose of ICS. They justify this approach based on the clinical and costeffectiveness data. A clinically important benefit of MART versus ICS + LABA as maintenance with SABA reliever was seen in terms of severe exacerbations and hospitalisations. NICE also considered evidence from economic studies and concluded that MART would be a cost-effective option for those that failed on ICS + LABA maintenance with a SABA reliever.<sup>1</sup>

Reliever doses with MART are considerably more expensive than with a SABA, and concern has been expressed that costs could escalate significantly, depending on their level of use. NICE note that if a person is frequently using their reliever, this is not consistent with controlled asthma and should prompt a review of the person's management.<sup>16</sup> Attachment 4 contains a summary of products licensed for MART, including the number of inhalers needed per month to provide the maintenance dose, which can be used to help identify people using more inhalers than expected.

In contrast with BTS/SIGN guidance, NICE recommend considering a MART regimen (with paediatric low maintenance ICS dose) in children and young people (5-16 years) whose asthma is uncontrolled on paediatric low dose of ICS + LABA. The recommendation includes the caveat of ensuring that the child or young person is able to understand and comply with the MART regimen. This recommendation is based on clinical data showing a benefit with respect to severe exacerbations. The small number of study participants (n=235), and lack of cost-effectiveness data led to a weaker recommendation being made ('consider' rather than 'offer').<sup>1</sup>

The NICE guideline committee discussed that, in their experience, some people are unsuited to a MART regimen, e.g. people who get less satisfactory symptom relief from ICS + LABA than from a SABA.<sup>1</sup> NICE did not include a recommendation on this. The issue of suitability for MART was discussed in stakeholder feedback. NICE state that if the prescriber and patient together do not feel that an individual can cope with a MART regimen, it should be bypassed as a treatment option.<sup>16</sup> NICE do not discuss what to do for LABA non-responders. However, it would not be clinically rational to offer a MART regimen, where the LABA is also the reliever. BTS/SIGN advises stopping the LABA if there is no response and considering increasing the dose of ICS.<sup>3</sup> Other factors that affect clinical efficacy, including inhaler technique and adherence, should also be considered.<sup>1,3</sup>

#### Age banding and ICS dosing

For pharmacological management, BTS/SIGN grade the supporting evidence within the following categories:

- Adults and adolescents over 12 years
- Children five to 12 years
- Children under five years<sup>3</sup>

BTS/SIGN include adolescents over 12 years with adults, which they consider to be in line with the inclusion criteria of many adult pharmacological studies.<sup>14</sup>

NICE use different age strata, specifically in regard to older children:

- Adults and young people over 17 years of age
- Children and young people aged five to 16 years
- Children under five years<sup>1</sup>

NICE chose the age groupings to reflect the organisation of services, with people older than 16 years old usually considered appropriate for treatment in adult services.<sup>16</sup>

NICE use budesonide as the comparator ICS for dose equivalency.<sup>16</sup>

For adults aged 17 and over NICE state that:

- Less than or equal to 400 micrograms budesonide or equivalent would be considered a low dose
- More than 400 micrograms to 800 micrograms budesonide or equivalent would be considered a moderate dose
- More than 800 micrograms budesonide or equivalent would be considered a high dose

For children and young people aged 16 and under:

- Less than or equal to 200 micrograms budesonide or equivalent would be considered a paediatric low dose
- More than 200 micrograms to 400 micrograms budesonide or equivalent would be considered a paediatric moderate dose
- More than 400 micrograms budesonide or equivalent would be considered a paediatric high dose<sup>2</sup>

It is important to note that for some ICS, the licensed dose for older children is the same as the adult dose. So, in some cases, the 'paediatric' dose equivalents stated above may not be appropriate for older children (i.e. they could be too low). NICE acknowledge that dosing in young people requires clinical judgment. They state that, in practice, the prescriber will choose dosages for young people aged 12 to 16 years (as well as children under five years) taking into account factors such as the severity of the condition and the person's size in relation to the average size of people of the same age.<sup>17</sup>

Those involved in producing local guidance for asthma should ensure clarity is provided as to where adolescents fit into local pathways. Clear dosage instructions for all age groups should be provided for the ICS-containing products recommended locally, whilst reminding prescribers of the need for clinical judgement, particularly when choosing appropriate ICS dosages in those aged under five years or aged 12–16 years. Pathway documents based on NICE guidance, that can be adapted and customised for local use, are available in attachments 6 to 8.

#### Further points about ICS recommendations in the NICE guidance

NICE used ICS potency tables from GINA to stratify the evidence for their guideline. The NICE guideline states that the tables (which are included in the full guideline, p.30 table 2 and table 3) can be used as a guide for dosage in clinical practice but should not be interpreted as a definitive statement of the relative potencies of the different inhaled steroids. However, some issues have been noted in relation to these tables, and NICE have issued a separate publication as an educational resource, which contains updated tables.<sup>17</sup> Clinicians should therefore refer to NICE's supplementary publication for further information on ICS dosing, rather the GINA tables reproduced in the full NICE guideline document. Issues with the GINA tables as reproduced in the full version of the NICE guideline are summarised in table 1.

	GINA (2015) tables as reproduced NG80 <sup>1</sup>	Supplementary NICE publication tables <sup>17</sup>		
Age groupings	Tables are divided into 'adults and adolescents' and 'children', which does not align with the age stratification used within the NICE guideline. In the NICE guideline, only adolescents ≥17 years are grouped with adults.	<ul><li>Table age groups are aligned with the NICE guideline.</li><li>N.B. Doses for adolescents from 12-16 years old are not included. Prescribers are advised to exercise their clinical judgement in selecting ICS doses for this age group.</li></ul>		
Type of beclometasone formulation	The tables are not explicit regarding the type of beclometasone formulation they refer to (i.e. standard particle (CFC) or extra-fine particle (HFA)).	When referring to beclometasone, the tables clearly state when they refer to standard particle or extra-fine particle formulations.		
Fluticasone propionate potency	The table relating to children implies that fluticasone propionate is equipotent with standard particle beclometasone. However, fluticasone propionate is usually regarded to be twice as potent as standard particle beclometasone. <sup>14</sup>	The doses of fluticasone propionate reflect its greater potency, in both the adult and child tables.		

Table 1. Issues with the ICS potency tables from GINA (2015) as reproduced in NICE NG80 (full version)

The NICE resource on ICS doses for asthma categorises fluticasone furoate (available only in a combination product with vilanterol, Relvar® Ellipta®) as:

- 100 microgram fluticasone furoate (as in Relvar® Ellipta® 92/22 microgram) moderate dose
- 200 microgram fluticasone furoate (as in Relvar® Ellipta® 184/22 microgram) high dose<sup>17</sup>

However BTS/SIGN classify the lower strength product (Relvar® Ellipta® 92/22 microgram) as medium dose ICS with some crossover into low dose.<sup>3</sup> There is also apparently conflicting information about fluticasone furoate potency in the SPC, which states that the 92/22 strength is for people requiring a low to mid dose of ICS with LABA, but which also states that this dose of fluticasone furoate once daily is approximately equivalent to fluticasone propionate 250 micrograms twice daily (a medium/moderate dose ICS).<sup>3,17,18</sup> The Marketing Authorisation holder of Relvar® Ellipta® explain this apparent conflict by referring to the different ways in which potency can be judged. They state that the lung function efficacy Relvar® Ellipta® 92/22 microgram is similar to a medium dose ICS + LABA, whilst the impact on the hypothalamic pituitary axis is consistent with a low dose LABA + ICS.<sup>19</sup>

Current asthma guidance from both NICE and BTS SIGN emphasise the importance of stepping down ICS to the lowest effective dose. Relvar® Ellipta® is not available in a lower strength than 92/22 microgram of fluticasone furoate/vilanterol, and concerns have been raised about the limited ability for stepping down treatment with this product.<sup>20</sup> The disadvantages of having to change both the device and the medication when stepping down treatment must be weighed against the product's potential benefits. These include once daily administration and better symptom control for some people compared to usual care<sup>\*</sup>.<sup>21</sup>

\*The effectiveness of fluticasone furoate/vilanterol over usual care has been demonstrated for asthma symptom control (primary end point, based on Asthma Control Test scores) in a large, real-world randomised controlled trial. The study did not demonstrate a difference in the exacerbation rate (a secondary end point). Almost one in five subjects in the fluticasone furoate/vilanterol combination inhaler group switched back to usual care.<sup>21</sup>

#### Differences in ICS dosage terminology

NICE and BTS/SIGN use different terminology to describe ICS dosage. NICE use the terms paediatric low dose, paediatric medium dose and paediatric high dose, and low, medium and high dose for adults. BTS/SIGN refer to very low dose, low dose, medium dose and high dose ICS. Very low dose through to medium doses are used in children and low dose to high dose ICS are used in adults. Despite the different terminology, the dosing information in the BTS/SIGN tables (tables 12 and 13 in the full version of the BTS/SIGN asthma guideline) and the tables in the NICE supplementary educational resource on ICS dosing is mostly consistent.<sup>3,17</sup>

#### **Role of tiotropium**

In both the BTS/SIGN and NICE guidelines, long-acting muscarinic antagonists (LAMAs) feature as an option to be considered in adults uncontrolled on combination therapy. The only LAMA currently licensed in asthma is tiotropium (as Spiriva® Respimat®).<sup>22</sup> BTS/SIGN classify tiotropium in asthma as specialist therapy, and state that all people whose asthma is not adequately controlled on initial or additional controller therapies should be referred for specialist care.<sup>3</sup> Neither NICE nor BTS/SIGN make a recommendation regarding use in children.<sup>1,3</sup>

The evidence review undertaken by NICE reported clinically important benefits with LAMAs in terms of severe exacerbations, but cost-effectiveness was considered to be highly uncertain. NICE therefore make a weaker 'consider' recommendation, and a research recommendation about the best additional maintenance treatment at this point in the pathway.<sup>1</sup> The recommendation is that a LAMA can be considered in those whose asthma is uncontrolled on a moderate maintenance ICS dose with a LABA (either as MART or a fixed-dose regimen), with or without an LTRA. Other options at this stage are increasing the ICS to a high maintenance dose (fixed-dose regimen), a trial of theophylline or seeking advice from a healthcare professional with expertise in asthma.<sup>1</sup>

Since the NICE asthma guideline was published, Spiriva® Respimat® has obtained a paediatric licence for asthma. It can be used as an add-on maintenance bronchodilator treatment in people aged six years and older with severe asthma who experienced one or more severe asthma exacerbations in the preceding year. The Summary of Product Characteristics (SPC) stipulates concomitant treatment that tiotropium should be used in addition to:

- In adults ICS (≥800 micrograms budesonide/day or equivalent) and at least one controller (e.g. LABA)
- In adolescents (12 17 years) ICS (>800 1600 micrograms budesonide/day or equivalent) and one controller or ICS (400 - 800 micrograms budesonide/day or equivalent) with two controllers
- In children (6 11 years) ICS (>400 micrograms budesonide/day or equivalent) and one controller or ICS (200 - 400 micrograms budesonide/day or equivalent) with two controllers<sup>22</sup>

Until further national guidance becomes available, a local decision will be needed regarding the use of LAMAs in children and adolescents. Where LAMA use is considered, the concomitant medication stipulated for these age groups in the Spiriva® Respimat® SPC would likely make it a specialist treatment.

#### Involving an asthma specialist

There are some differences between the chronic asthma pharmacological treatment pathways of NICE and BTS/SIGN regarding referral.

For adults (≥17 years), NICE advise that primary care practitioners should consider seeking advice from a healthcare professional with expertise in asthma for people that are uncontrolled on a moderate dose ICS plus a LABA, with or without LTRA.<sup>1</sup> BTS/SIGN recommend referral at a similar point in their pathway, but referral is expected, rather than an option; they state that high-doses of ICS should only be used after referring the person to specialist care.<sup>3</sup> The Clinical Knowledge Summary for asthma makes the pragmatic suggestion that it may be appropriate to seek specialist advice where high dose corticosteroid treatment is required, depending on the experience of the prescriber.<sup>8</sup>

For children aged five to 16 years, NICE advise that primary care practitioners should consider seeking advice from a healthcare professional with expertise in asthma for children that are not controlled on a paediatric moderate dose ICS with a LABA.<sup>1</sup> Again, the point at which BTS/SIGN recommend referral is similar, but the wording is stronger; they state that children on a medium or high ICS dose should be under the care of a specialist paediatrician for the duration of the treatment.<sup>3</sup> The Clinical Knowledge Summary for asthma notes that further treatments for children beyond paediatric moderate dose ICS are usually carried out under specialist supervision.<sup>8</sup>

NICE has a further pathway for the youngest age group of children (those under five years). Evidence on escalation of treatment in this age group is lacking. The recommendation to seek a specialist opinion comes much earlier in this pathway, at the point of stopping an LTRA (where the child will be on paediatric low dose ICS maintenance treatment).<sup>1</sup>

The NRAD (see 'Safety' section) recommended that those that have required more than two courses of systemic corticosteroids, oral or injected, in the previous 12 months or those needing treatment at BTS/ SIGN step four or five (now referred to as 'Specialist therapies' stage in latest BTS/SIGN guidance) to achieve control must be referred to a specialist asthma service.<sup>4</sup>

### Review

The frequency of review will vary depending on individual factors such as severity of the disease. The minimum requirements for review are:

- Annual review of asthma (but more frequently where appropriate)<sup>3,23</sup>
- After starting or adjusting medicines for asthma, where the response to treatment should be reviewed after four to eight weeks<sup>1</sup>
- When asthma worsens people should have a personal asthma action plan which clearly sets out when to seek medical advice<sup>1,3,23</sup>
- After an asthma attack<sup>1,23</sup>
- If the person's asthma is not well controlled.\* Ensure that the person understands that regularly needing 'as required' rescue medication (whether as SABA, or LABA+ICS) is not consistent with good asthma control and means that they need a review
- If the person's asthma has been controlled with their current maintenance therapy for at least three months, as they may be eligible to have their maintenance treatment decreased (see below)<sup>1</sup>

\*Consider the potential for allergic bronchopulmonary aspergillosis in those with poorly controlled or corticosteroid-dependant asthma. The condition has an estimated prevalence of 1-2.5% among people with asthma.<sup>24</sup>

As well as monitoring the percentage of patients reviewed annually, practices should consider focusing on particular groups such as those overusing bronchodilators, people on higher dose therapies, those with asthma attacks or from groups with more complex needs.<sup>3</sup>

Asthma control should be monitored at every review.<sup>23</sup> The latest BTS/SIGN asthma guidance includes a summary table of the components of an asthma review (see Table 2).

Parameters	Suggested assessment	
	Bronchodilator use	
Current symptom control	Validated symptom score	
	Time off work/school due to asthma	
	Past history of asthma attacks	
Future risk of	Oral corticosteroid use	
attacks*	Prescription data: frequent SABA and infrequent ICS	
	Exposure to tobacco smoke	
Tasts /invastigations	<ul> <li>Lung function (spirometry or by peak expiratory flow)</li> </ul>	
Tests/ investigations	Growth (height and weight centile) in children	
	Inhaler technique	
Managamant	Adherence (self-report, prescription refill frequency)	
Management	Non-pharmacological management (trigger avoidance, breathing exercises)	
	Pharmacological management- consider multimorbidity and polypharmacy	
Supported self-	<ul> <li>Education/discussion about self-management</li> </ul>	
management	Provision/revision of a written personalised asthma action plan	

Table 2. (	Components	of an as	thma rev	view (from	<b>BTS/SIGN</b>	asthma	guideline	2019) <sup>3</sup>
	components	UI all as	unna i ev		D13/31014	astiinia	guiueime	2017)

\*For further information about risk factors for exacerbations, see attachment 5.

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The NICE guideline uses the following pragmatic thresholds to define uncontrolled asthma:

- Three or more days a week with symptoms or
- Three or more days a week with required use of a SABA for symptomatic relief or
- One or more nights a week with awakening due to asthma.<sup>1</sup>

When reviewing an individual's asthma control, both NICE and BTS/SIGN suggest using a validated questionnaire.<sup>1,3</sup> For adults, NICE give the examples of the Asthma Control Questionnaire or Asthma Control Test, but not the Royal College of Physicians (RCP) three questions, as they found no RCT evidence to support the latter.<sup>16</sup> BTS/SIGN refer to the RCP three questions as direct questions for use in day-to-day clinical practice, but highlight that it is not a validated control questionnaire. Where used, answering no to all three questions is consistent with controlled asthma. Any positive answers should prompt further assessment.<sup>3</sup>

NICE found insufficient evidence to make a recommendation on the use of validated paediatric questionnaires.<sup>16</sup> BTS/SIGN note that the Asthma Control Questionnaire is validated in children older than five years, the Childhood Asthma Control Test is valid for four to 11 year olds, and the Paediatric Asthma Quality of Life Questionnaire is validated for seven to 11 year olds.<sup>3</sup>

### **Decreasing maintenance treatment**

Decreasing therapy once asthma is controlled is recommended, but often not implemented leaving some people overtreated.<sup>3</sup> As well as the clinical implications of overtreatment, there are significant financial implications, and costs can increase significantly as treatment escalates with increasing doses of ICS or the addition of further agents.

Consider decreasing maintenance therapy once a person's asthma has been controlled with their current maintenance therapy for at least three months.<sup>1</sup>

Clinicians may also wish to consider the general principles of stepping down asthma treatment described in the GINA guideline, which is summarised in attachment 5.<sup>12</sup>

When reducing maintenance therapy, stop or reduce the dose of medicines in an order that takes into account the clinical effectiveness when introduced, side effects and the person's preference.<sup>1</sup>

With regard to ICS specifically:

- Aim for the lowest dose required for effective control.<sup>1,3</sup>
- Reduce the dose slowly, as individuals deteriorate at different rates. Consider reductions every three months, decreasing the dose by approximately 25–50% each time.<sup>3</sup>
- Only consider stopping ICS treatment completely for people who are using low dose ICS alone as maintenance therapy and are symptom free.<sup>1</sup>

The consultation should include:

- A discussion of the potential risks and benefits of decreasing maintenance therapy.
- Agreement with the person (or their family/carer if appropriate) on how the effects of decreasing maintenance therapy will be monitored and reviewed, including self-monitoring and a follow-up with a healthcare professional.
- Reviewing and updating of the person's asthma action plan.<sup>1</sup>

People on higher doses of ICS, and/or on several asthma medicines are more likely to be under the care of an asthma specialist. It may be useful to consider who makes decisions about decreasing maintenance treatment in such patients, and whether there is a clear process with good communication between primary and secondary care locally.

### Self-management

People with asthma should be offered self-management education, including a written personalised asthma action plan (PAAP), which details action to take if their control deteriorates.<sup>1,3</sup> Asthma action plans for adults and children can be found on the Asthma UK website (<u>www.asthma.org.uk</u>), available in English and Welsh languages, along with practical advice for people with asthma and health care professionals on how best to use them. This includes a section for health care professionals on filling in patients' asthma action plans. Ensure that the PAAP includes advice appropriate to the type of maintenance regiment the person is on, which will differ for those on MART regimens compared with those on traditional fixed dose maintenance regimens.

In adults, written PAAPs may be based on symptoms and/or peak flows, whereas symptom-based plans are generally preferable for children.<sup>3</sup> BTS/SIGN have recently updated their advice on supported self-management. For adults not using a MART regimen, prescribers should now consider advising the person to quadruple their ICS at the onset of an asthma attack and for up to 14 days in order to reduce the risk of needing oral steroids. The following action points are suggested in PAAPs for adults:

- Peak expiratory flow (PEF) <80% best: quadruple inhaled corticosteroids
- PEF <60% best: commence oral steroids and seek same-day medical advice
- PEF <50% best: seek urgent medical advice<sup>3</sup>

Consider adherence before recommending increasing ICS as people who are highly adherent (>90%) may have a ceiling effect and gain no additional benefit from increasing ICS at the onset of an attack. For people who are already on a high dose ICS, weigh the benefit/risk ratio of recommending quadrupling ICS at the start of an asthma attack. This group are usually under the care of an asthma specialist, who can advise on the most appropriate PAAPs for such individuals. For those on fixed-dose combination inhalers (not as MART), increasing the dose of ICS may best be achieved by prescribing an additional single ICS inhaler, which should be labelled accordingly.<sup>3</sup>

For children, evidence to inform best practice regarding increasing the ICS dose to abort an attack is more limited. In their 2017 guideline, NICE state that quadrupling the dose of ICS can be considered within a self-management plan for children and young people.<sup>1</sup> However, following a review of the evidence, NICE updated the guideline in February 2020 to state that for children and young people aged 5 to 16 advice should be included in their self-management programme to contacting a healthcare professional for a review if their asthma control deteriorates. If ICSs have not been taken consistently, explain that restarting regular use may help to regain control of their asthma. The evidence for increasing ICS doses to self-manage deteriorating asthma control in children and young people aged 5 to 16 is limited.<sup>1</sup>

After a self-managed exacerbation, patients should see their primary care healthcare professional for a semi-urgent review (e.g. within one to two weeks), for assessment of symptom control and additional risk factors for exacerbations, and to identify the potential cause of the exacerbation. The written asthma action plan should be reviewed to see if it met the person's needs. If the history suggests that the exacerbation occurred on a background of long-term, poorly controlled asthma (provided inhaler technique and adherence have been checked) a step up in treatment is indicated.<sup>12</sup>

### Adherence

If control is found to be suboptimal, it is important to consider adherence and to review the person's inhaler technique.<sup>1,3</sup> Non-adherent behaviour is traditionally categorised into unintentional and intentional. Unintentional non-adherence can arise from forgetfulness, misunderstanding and confusion.

Intentional non-adherence occurs when the person decides to deviate from the prescribed treatment regimen.<sup>25</sup> Incorrect use of an inhaler device could be unintentional (e.g. not knowing the correct technique or lacking the dexterity needed to use a particular device) or could be intentional (e.g. deciding not to use a spacer because it is inconvenient or conspicuous).

Both NICE and BTS/SIGN highlight that healthcare professionals should recognise that non-adherence is common and should routinely assess adherence in a non-judgemental way.<sup>2,3,26</sup> Any interventions to support adherence should be considered on a case-by-case basis and should address the concerns and needs of the individual. BTS/SIGN provide some useful examples of open-ended questions to help stimulate open discussion, such as:

- How do you think that the inhaler is helping you control your asthma?
- How much bother do you have from side effects?
- Some people worry about taking regular medication... what do you think?
- How often did you use your preventer inhaler last week?<sup>3</sup>

It is also important to elicit the individual's own goals regarding their asthma, as these may differ from conventional medical goals.<sup>12</sup>

Records of prescription re-ordering, pharmacy patient medication records and return of unused medicines can be used to identify potential non-adherence and people needing additional support.<sup>26</sup> For example, checking the frequency of SABA ordering and preventer medication ordering could help to identify people that are not using their medication optimally, and may be at greater risk of an asthma attack.

Inhaler technique should be observed and advised upon regularly. NICE explicitly state that this should occur:<sup>2</sup>

- At every consultation relating to an asthma attack, in all care settings
- When there is deterioration in asthma control
- When the inhaler device is changed
- At every annual review
- If the person asks for it to be checked

Local asthma guidelines should include a range of inhaler device options, so that the choice can be tailored to the individual's preference and ability. People should be able to move through the treatment pathway without excessive changes to their device. For most people with asthma, treatment will consist of more than one type of inhaled medication; ideally these should be delivered through the same or similar devices that require the person to master one only technique for taking their inhalers.

NHS branded inhaler technique videos and leaflets that can be embedded on local websites are available to subscribers at <a href="https://www.prescqipp.info/our-resources/webkits/respiratory-care/">https://www.prescqipp.info/our-resources/webkits/respiratory-care/</a>

## Safety

#### National Review of Asthma Deaths Report

The NRAD report, published in May 2014, was based on a review of asthma deaths occurring between February 2012 and January 2013.<sup>4</sup> The primary aim of NRAD was to understand the circumstances surrounding asthma deaths in the UK in order to identify avoidable factors and make recommendations to improve care and reduce the number of deaths. Data was analysed on 195 people who were thought to have died from asthma and the key findings relate to this group.

The report found that the majority of people who died from asthma (n=112, 57%) were not recorded as being under specialist supervision during the 12 months prior to death. Only 83 (43%) were managed in secondary or tertiary care during this period; therefore, there is significant work that can be done in the primary care setting to improve the care of asthma patients. Many of the recommendations related to prescribing and medicines usage.

The key recommendations were:

- Patients using more than 12 SABA inhalers in the past 12 months should be invited for an urgent asthma review with the aim of improving their asthma through education and change of treatment if required.
- An assessment of inhaler technique to ensure effectiveness should be routinely undertaken and formally documented at annual review and checked by the pharmacist when a new device is dispensed.
- Non-adherence to preventer ICS is associated with increased risk of poor asthma control and should be continually monitored.
- The use of combination inhalers should be encouraged. Where LABA bronchodilators are prescribed for people with asthma, they should be prescribed with an ICS in a single combination inhaler.

Searches to support practices in identifying some of these groups of patients are available at <a href="https://www.prescqipp.info/our-resources/bulletins/bulletin-251-asthma/">https://www.prescqipp.info/our-resources/bulletins/bulletin-251-asthma/</a> With respect to the number of SABA inhalers ordered, practices should consider searching for people ordering less than 12 per year, who are still likely to be over-relying on their SABA. People using even three to six SABA inhalers (200 dose canister) per year may be at greater risk of an exacerbation, with the risk increasing progressively with number of canisters used.<sup>27</sup> Those using the highest number of canisters should be prioritised for urgent review.

An 'Asthma Slide Rule' has been developed by Asthma Right Care (funded by AstraZeneca).<sup>28</sup> It can be used to visualise what the number of SABA inhalers ordered per year might represent in terms of weekly or daily SABA usage. It aims to stimulate conversation about over-reliance on SABAs in asthma management. It is available at https://www.pcrs-uk.org/resource/asthma-slide-rule.

## High dose ICS

The benefits of an ICS outweigh the risks when used in clinically effective doses, however, long-term high doses may cause systemic side effects. The British National Formulary (BNF) advises the following:

"Consider giving a 'steroid card' to support communication of the risks associated with treatment, and specific written advice to consider corticosteroid replacement during an episode of stress, such as severe intercurrent illness or an operation, to patients using greater than maximum licensed doses of ICS. Use of other corticosteroid therapy (including topical) or concurrent use of drugs which inhibit corticosteroid metabolism should be taken into account when assessing systemic risk."<sup>6</sup>

The London Respiratory Network have developed a high dose ICS safety card for adults, which should be given to any patients aged 12 and over taking high doses of ICS.<sup>7</sup> Both NICE (see the educational resource on ICS doses) and BTS/SIGN have provided advice as to which doses of ICS are considered to be high dose (tables 12 and 13).<sup>3,17</sup>

### **ICS in children**

BTS/SIGN advise that medium-dose ICS (paediatric high dose in NICE terminology) or high-dose ICS may be associated with systemic side effects in children. These may include growth failure and adrenal suppression. With careful ICS dose adjustment, the risk of adverse effects is likely to be outweighed by their ability to reduce the need for multiple bursts of oral corticosteroids for acute asthma attacks.

- Monitor growth (height and weight centile) of children with asthma on an annual basis
- Use the lowest dose of ICS that maintains asthma control
- For children treated with medium-dose ICS (paediatric high dose in NICE terminology) or high-dose ICS:
  - » Specific written advice about steroid replacement in the event of a severe intercurrent illness or surgery should be part of the management plan
  - » The child should be under the care of a specialist paediatrician for the duration of the treatment<sup>3</sup>

## Use of LABAs

National guidance from NICE, BTS/SIGN and the Medicines & Healthcare products Regulatory Agency (MHRA) agree that LABAs should always be prescribed with ICS in asthma, and only when ICS alone are insufficient.<sup>1,3,31</sup> Combination inhalers should be used.<sup>2,4,31</sup> LABAs should not be initiated in people with rapidly deteriorating asthma. They should be prescribed at the lowest effective dose, reviewed regularly and stopped if there is no benefit.<sup>29</sup>

## Risk of airway obstruction from aspiration of loose objects

Due to the risk of aspiration, the MHRA advise reminding patients to check and remove the mouthpiece cover from their pressurised metered dose inhaler (pMDI) properly before inhaling a dose, and to shake the inhaler to remove loose objects that may have become trapped in the inhaler during storage. The mouthpiece cover should be replaced securely after use.<sup>30</sup>

## **Community pharmacy services**

Community pharmacy services can support people in getting the most from their asthma medication. Information about the Community Pharmacy New Medicine Service (NMS) and Medicine Use Reviews (MURs) can be found in attachment 1, and a Patient Information Leaflet on the NMS can be found in attachment 2. The MUR service is being phased out during 20/21. Community pharmacists can undertake up to 100 MURs in 2020/21. At least 70% of MURs have to be targeted to patients taking high risk medicines and those recently discharged from hospital. High risk medicines for MURs are NSAIDs, anticoagulants (including low molecular weight heparin), antiplatelets, and diuretics. The Asthma UK website contains information entitled 'Make the most of your pharmacist', which also discusses these services, and is available from Asthma UK at: https://www.asthma.org.uk/advice/ manage-your-asthma/pharmacist/

Commissioners should consider further ways in which local community pharmacy services could be developed to support implementation of NRAD recommendations and improve asthma care. A range of potential options has been compiled by the Pharmaceutical Services Negotiating Committee (PSNC), such as case finding for SABA overuse or preventer treatment underuse.<sup>31</sup>

## **Environmental considerations**

The NHS Long Term Plan outlines environmental commitments in line with national carbon and air pollution reduction targets.<sup>32</sup> It has been estimated that propellants in pMDIs are responsible for around 3.5% of all NHS emissions,<sup>33</sup> and the NHS plans to reduce this with a shift to lower carbon inhalers.<sup>32</sup>

Dry powder inhalers (DPIs) have a low carbon footprint compared with pMDIs. The estimated carbon footprint of a DPIs is 20g CO<sub>2</sub> equivalents per dose, compared with 500g CO<sub>2</sub> equivalents per dose for pMDIs. This difference is largely due to the lack of propellants in DPIs. The hydrofluorocarbon (HFC) propellants used in pMDIs are powerful greenhouse gases and can contribute to global warming. Used pMDI canisters still contain propellants and should be returned to a pharmacy to dispose of in an environmentally safe way. As well as providing safe disposal, some pharmacies also participate in inhaler recycling schemes (but not spacer devices).<sup>5</sup>

Whilst DPIs are suitable for many people, some people (e.g. young children, or those unable to breathe in quickly and deeply) specifically require a pMDI, often with a spacer. NICE has produced a patient decision aid (for people aged 17 years and older with asthma) and user guide, to help people consider the different features and attributes of various inhaler devices, including the inhaler carbon footprint, when choosing their inhaler device.<sup>5,33</sup>

The Respimat® device is classed as a soft mist inhaler (SMI). The canisters do not contain a propellant, so they are a lower carbon footprint option. Reusing the device (with up to six refill cartridges) further lowers the carbon footprint.<sup>34</sup> The NICE patient decision aid does not however include SMIs. This is because the one SMI product currently licensed in asthma (Spiriva® Respimat®) is an option in only a limited number of people with asthma.<sup>5</sup>

It is important to recognise that medicines optimisation measures that promote effective treatment, reduce over-reliance on SABAs and discourage waste are also key components of environmentally (as well as clinically) responsible medicines usage.

To support the change to lower carbon footprint inhalers, the Primary Care Network (PCN) Directly Enhanced Service (DES) specification for structured medication reviews and medicines optimisation makes a requirement of PCNs to "actively work with their CCG to optimise the quality of prescribing of metered dose inhalers, where a low carbon alternative may be appropriate".<sup>5</sup> The specification states that the NHS has committed to reducing the carbon impact of inhalers used in the treatment of respiratory conditions by 50%.<sup>35</sup> All inhaler prescriptions, Structured Medication Reviews or planned Asthma Reviews taking place in primary care should consider moving or facilitating patients to lower carbon options where it is clinically appropriate to do so.<sup>35</sup>

There is an Impact and Investment Fund indicator (IIF) for pMDI prescriptions as a percent (%) of all inhaler prescriptions (excluding salbutamol). The lower threshold value is 53% pMDIs as a total of all inhaler prescriptions (excluding salbutamol) and the upper threshold value is 45%.<sup>35</sup>

### Other prescribing considerations

- Prescribe inhalers by brand and device to ensure that the person receives the intended inhaler that they are familiar with and have been trained to use properly.<sup>3</sup>
- When making a formulary choice, consider the ability to step down treatment and minimise the range of inhaler types the patient needs master.
- Depending on how MART is positioned in local guidance, it may be important to consider how easily people can move from low dose ICS + LABA as a fixed-dose regimen to a MART regimen when making formulary choices.
- Where possible prescribe the same type of inhaler device to deliver preventer and reliever treatments. Prescribing mixed inhaler types may cause confusion and lead to increased errors in use.<sup>3</sup>
- The lowest cost product that is appropriate and acceptable to the individual should be used.
- When using ICS, use of other corticosteroid therapy (including topical) or concurrent use of drugs which inhibit corticosteroid metabolism should be taken into account when assessing systemic risk.<sup>6</sup>
- Ensure that people using a pMDI also receive a spacer where appropriate. Provide information and training on how to use and care for the spacer <u>https://www.prescqipp.info/our-resources/bulletins/</u><u>bulletin-221-respiratory-spacer-videos/</u> The following groups always need a spacer with a pMDI:
  - » All infants and young children need to use a spacer with an appropriately sized mask. They should continue to use a mask until they can breathe reproducibly using the spacer mouthpiece, making a good seal.<sup>3</sup>
  - » Adults who have trouble co-ordinating the 'press and breathe' action needed with a pMDI. Spacers with adult-sized masks are available for adults that cannot create a good seal with a mouthpiece.
  - » Adults taking high doses of corticosteroids via a pMDI.<sup>3</sup>

- Ensure that preventer inhalers with extra-fine particle formulations (e.g. Qvar®, Fostair®) are prescribed at doses that reflect their greater potency.
- For people on a MART regimen who use a reliever before exercise, consider providing a separate SABA for this purpose.<sup>36-38</sup>
- Consult local experts to consider if there are circumstances that justify issuing a separate SABA inhaler to people on MART therapy in case of asthma attack. Some specialists advise this in case of acute situations where the maximum licensed dose of MART has been reached,<sup>1</sup> or so that the person can use tidal breathing with a pMDI and spacer during an asthma attack. Potential harms of this approach include the risk of confusing the patient or encouraging inappropriate use of MART and SABA routinely, when the person should be contacting a healthcare professional.<sup>16</sup>
- Not all strengths of Symbicort<sup>®</sup>, Fostair<sup>®</sup>, DuoResp Spiromax<sup>®</sup> and Fobumix<sup>®</sup> are licensed for MART; the highest strength preparations are licensed as fixed-dose maintenance therapy only.<sup>6</sup> Ensure people moving from a MART regimen to a higher strength preparation of these inhalers (or anyone moving from MART to a fixed dose maintenance with SABA) understand the difference in their treatment regimen.
- Use specific instructions for prescriptions and pharmacy labels for inhalers. Avoid non-specific
  instructions, such as 'as directed'. As well as being documented in the patient record and PAAP, it
  should be clear from the instructions on the prescription for a combination inhaler what type of
  regimen the person is prescribed (i.e. fixed dose or MART). Practices may wish to add customised
  formularies to their clinical system (particularly for MART) to ensure that clear directions can be
  easily selected.
- Documentation of MART in the patient record should include an appropriate read code, e.g. 'Single inhaler maintenance and reliever therapy started'.

### Costs

A spreadsheet of inhalers licensed in asthma, which includes the cost per device and per dose, is available as a support resource in attachment 9. The spreadsheet can be filtered and sorted according to a range of product features (e.g. therapeutic class, age licensed from, MART licence), and can be used to support the formulary decision making process when comparing the cost of treatments.

## Prescribing review and potential savings

The focus should be on reviewing patients and optimising their treatment, including decreasing maintenance treatment where appropriate. Overtreatment is costly and presents unjustified clinical risks, so is a clear target area to tackle in terms of medicines optimisation. Better management with regular clinical review, as recommended in national guidance and outlined above, may provide greater cost-savings and better quality care.

The clinical review process should include consideration of whether the person is being treated with the cost-effective choices recommended in local guidance. Taking this type of integrated approach means that changes to treatment can be considered holistically and discussed face-to-face. NICE have specifically advised that, where their recommendations in NG80 represent a change from traditional clinical practice, people whose asthma is well controlled on their current treatment should not have their treatment changed purely to follow the guidance.<sup>2</sup> This advice is compatible with ensuring that people are reviewed appropriately, and should not be a barrier to promoting individual review of asthma management in accordance with the most up-to-date advice.

Undertaking individual review, as outlined in national guidance and this bulletin, would provide ample opportunity to consider and discuss treatment changes where they are indicated. This should include consideration and discussion of options that would bring the person's treatment in line with the new locally agreed treatment pathway, where this is available. Changes based on cost-effectiveness alone may also be considered, if they are appropriate and acceptable to both the patient and the clinician.

Examples of some of the savings available nationally are estimated below.

A 25% shift from low dose ICS + LABA to LTRA (representing a gradual shift to the NICE asthma pathway) could save £43,285 per year per 100,000 patients across England and Wales. **Total annual savings are approximately £27.3 million nationally.** 

Savings are available for stepping down treatment from high dose ICS, where clinically appropriate. For example, stepping down 10% of people prescribed high dose ICS to moderate dose ICS could save £3,786 per year per 100,000 patients across England and Wales. Total annual savings are approximately £2.3 million nationally.

An asthma treatment pathway costing tool <u>https://pdata.uk/#/views/</u> <u>ChronicAsthmaTreatmentPathwayCostingTool/IntroNotes?:iid=1</u> can be used at a local level to undertake a wide variety of cost comparisons and estimate the impact of formulary changes.

### Summary

At present, two sets of national guidelines on asthma management (from NICE and BTS/SIGN) are available in the UK.<sup>1-3</sup> For the most part, the guidelines make similar recommendations, however there are some notable differences, which have the potential to create uncertainty for clinicians about the best way to manage chronic asthma. Clear local guidance, developed with input from local asthma experts, is therefore of key importance to avoid confusion and to support prescribers in primary care (and other care settings).

When making formulary choices, local decision-makers should consider the ease with which people can move within the treatment pathway. A choice of cost-effective treatment options should be included to enable treatment to be tailored to the individual. Medicines optimisation in asthma should focus on quality and safety, with cost-effectiveness integrated into the review process.

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## Additional PrescQIPP resources

	Bulletin	https://www.prescqipp.info/our-resources/bulletins/bulletin-251-
×	Implementation tools	asthma/
	Data pack	https://pdata.uk/#/views/B251_Asthmaupdate/FrontPage?:iid=1

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