British Thoracic Society

ring and chronic asth

NICE National Institute for Health and Care Excellence

Healthcare Improvement Scotland | SIGN Evidence-based clinical guidelines

line – deadline for co asthmachronicma

Checklist for submitting comments

- Use this comments form and submit it as a **Word document (not a PDF)**.
- **Do not submit further attachments** such as research articles, or supplementary files. We return comments forms that have attachments without reading them. You may resubmit the form without attachments, but it must be received by the deadline. You are welcome to include links to research articles or provide references to them
- Complete the disclosure about links with, or funding from, the tobacco industry.
- Include **document name, page number and line number** of the text each comment is about.
- Combine all comments from your organisation into 1 response form. **We cannot accept more than 1 comments form from each organisation**.
- **Do not** paste other tables into this table – type directly into the table.
- Ensure each comment stands alone; **do not** cross-refer within one comment to another comment.
- **Clearly mark any confidential information or other material that you do not wish to be made public with underlining and highlighting. Also, ensure you state in your email to NICE, and in the row below, that your submission includes confidential comments.**
- **Do not name or identify any person or include medical information about yourself or another person** from which you or the person could be identified as all such data will be deleted or redacted.
- Spell out any abbreviations you use.
- **We do not accept comments submitted after the deadline stated for close of consultation.**

Note: We reserve the right to summarise and edit comments received during consultations, or not to publish them at all, if we consider the comments are too long, or publication would be unlawful or otherwise inappropriate. Where comments contain confidential information, we will redact the relevant text, or may redact the entire comment as appropriate.

Comments received during our consultations are published in the interests of openness and transparency, and to promote understanding of how recommendations are developed. The comments are published as a record of the comments we received, and are not endorsed by NICE, its officers or advisory Committees.

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	Please read the checklist above before submitting comments. We cannot accept forms that are not filled in correctly. We would like to hear your views on the draft recommendations presented in the guideline, and any comments you may have on the rationale and impact sections in the guideline and the evidence presented in the evidence reviews documents. We would also welcome views on the Equality Impact Assessment. In addition to your comments below on our guideline documents, we would like to hear your views on these questions. **Please include your answers to these questions with your comments in the table below.** 1. Would it be challenging to implement of any of the draft recommendations? Please say why and for whom. Please include any suggestions that could help users overcome these challenges (for example, existing practical resources or national initiatives. 2. Would implementation of any of the draft recommendations have significant cost implications? 3. The updated recommendations in this guideline will require the NICE indicator on asthma diagnosis (NM166), currently included in NHS England's Quality and Outcomes Framework (QOF AST011), to be amended. The current wording for NICE indicator NM166 is: *The percentage of patients with asthma on the register from (start date) with a record of spirometry and one other objective test (FeNO or reversibility or variability) between 3 months before or 3 months after diagnosis*. Please indicate whether you would prefer an updated indicator to focus on the initial diagnostic test (option A) or any objective test (option B) around the time of diagnosis, and why: A. The percentage of patients with asthma on the register from (start date) with a record of fractional exhaled nitric oxide (FeNO) (adults and children) or blood eosinophil count (adults) or spirometry with bronchodilator reversibility (children), between 3 months before or 3 months after diagnosis. B. The percentage of patients with asthma on the register from (start date) with a record of an objective test (eosinophil count, fractional exhaled nitric oxide (FeNO), spirometry, peak flow with bronchodilator reversibility, bronchial responsiveness (in adults), skin prick test or blood IgE level (in children)) between 3 months before or 3 months after diagnosis. See Developing NICE guidance: how to get involved for suggestions of general points to think about when commenting.

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Organisation name (if you are responding as an individual rather than a registered stakeholder please specify).	UK Clinical Pharmacy Association (UKCPA) and Royal Pharmaceutical Society (RPS)
Disclosure (please disclose any past or current, direct or indirect links to, or funding from, the tobacco industry).	None
Confidential comments (Do any of your comments contain confidential information?)	No
Name of person completing form	Prof Anna Murphy (on behalf of UKCPA-Respiratory Committee – Dr Toby Capstick, Patrick Wilson, Ravijyot Saggu, Helen Edwards, Sarah Poole)

Comment number	**Document** [e.g. guideline, evidence review A, B, C etc., methods, EIA]	**Page number** **'General'** for comments on whole document	**Line number** **'General'** for comments on whole document	**Comments** • Insert each comment in a new row. • Do not paste other tables into this table, because your comments could get lost – type directly into this table. • Include section or recommendation number in this column.
1	Guideline	1	General	Title page 'who is it for' – this states 'GPs and nurses or HCPs in secondary and tertiary care'. This has not included Pharmacists who work broadly in primary care (both primary care network/GP setting, community pharmacy or community services where they are involved in monitoring, prescribing for and diagnosis of asthma) or other staff that work in community services (such as community respiratory teams and virtual wards. Suggest the wording is changed to be more inclusive to reflect this
2	Guideline	4	6	1.1.1 Clinical history - To specifically include 'upper airway disease such as nasal disorders'
3			14	1.1.2 'Do not confirm a diagnosis of asthma without a suggestive clinical history and a supporting objective test' – this may be misconstrued as diagnosis can be made by a single objective test. It is worth stating that often more than one objective test is required for diagnosis and clinicians require collective information along with the clinical history to make the correct diagnosis– see feedback point

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				echoed in below row
4	Guideline	5	22	Recommendation 1.2.1 We are concerned that asthma diagnosis in adults can be made by a blood eosinophil count measurement **or** a FeNO measurement for a number of reasons: - A raised blood eosinophil above the reference range is not always diagnostic of asthma (e.g allergic rhinitis, inflammatory diseases)? There are other conditions (and drug induced) where eosinophils are elevated that are not diagnostic of asthma. Consider clarifying this to rule out other causes. - Currently the draft guidance suggests that FeNO alone with asthma suggestive symptoms is sufficient to obtain an asthma diagnosis. FeNO is raised in other conditions and other factors aside from asthma and is not valuable in those patients who smoke who may also have asthma. - We feel that asthma diagnosis should continue to include reference to the presence of variable airflow obstruction. FeNO and blood eosinophils are helpful in addition to support the diagnosis of asthma and a particular phenotype. - Establishing an accurate diagnosis is key to ensure unnecessary escalation of medication with potential adverse effects to patients and cost to the NHS.
5	Guideline	6	1	1.2.3 If diagnosis is uncertain then bronchial hyper-responsiveness tests will be required. Resources will be required to implement this recommendation as it usually requires referral to hospital for these tests to be carried out using specific pharmacological agents and cannot routinely be undertaken in primary care.
6	Guideline	6	11	Rec 1.2.6 Children 5-16 years – skin prick testing: this will have resource implication – not usually done in primary care and would require referral to hospital and adequate anaphylaxis/resuscitation facilities available during test
7	Guideline	8	16	1.5.1 Monitoring asthma control, suggest changing 'amount of reliever inhaler used' to 'amount of reliever **doses** used', as AIR/MART regimens do not have a separate reliever inhaler.
8	Guideline	8	22	1.5.3 The recommendation to not use PEFR is confusing especially when they are recommended as part of a personalised asthma action plan. Although PEFR not recommended for regular monitoring the use of PEFR at certain times to help access control is useful, for example – baseline best PEFR and intermittent measurement when symptoms decline.
9	Guideline	8		1.5.4 'Consider using FeNO' – There is already little uptake of FeNO testing in primary care due to concerns over the cost of equipment and mouthpieces and unfortunately this wording doesn't sound like it will change practice – we understand the word 'consider' is used based on the strength of evidence available but could this recommendation be reworded to give more emphasis to the clinical utility to support review and adherence?
10	Guideline	8	28	1.5.5 Suggest the wording around inhaler technique is changed to ensure HCPs check and optimise

				inhaler technique
11	Guideline	9	19	1.6.1 It would be useful to add further examples here as well as obesity, e.g. GORD, nasal disease also include optimisation of co-multimorbidity
12	Guideline	9	20	1.6.1 Please consider changing the terminology 'lack of adherence' to 'sub-optimal medicine adherence', as some people overuse inhalers (particularly SABAs). Lack of adherence suggests that underuse is the only problem.
13	Guideline	10	15	1.6.4 Consider adding wording: "taking into account the local formulary"
14	Guideline	10	16	1.6.4 consider changing the wording to 'an assessment of correct **inhaler** technique and ability to use the inhaler device' – this accounts for dexterity and ability to actuate the device as well as the correct inspiration. The patient preference bullet point is listed last, suggest moving this further up to give it more importance
15	Guideline	11	1	1.6.5 Give people information about their inhalers – please also include that information should be given on rough duration the inhaler should last to manage patient expectations e.g. one inhaler shouldn't last them for 6 months.
16	Guideline	11	11	1.6.6 Statement: For example; when a person switches to a generic device – what does this mean? As all inhalers would be prescribed as brand name including for device
17	Guideline	11	15-17	1.6.7 Although we agree that using one type of device to deliver preventer and reliever treatments this is not always possible due to device availability (e.g. no Reliever device available to match preventer) and may not be preferred by the patient. Please amend to where possible.
18	Guideline	11	18-19	Some areas are introducing inhaler recycling schemes, and it is hoped that these may become more widely available. Suggest amending this text accordingly, e.g. 'Encourage people to take their used (once finished/expired) inhalers to their pharmacy for disposal**, or inhaler recycling where available**'
19	Guideline	12	12	1.7.2 Whilst we support the use of AIR for patients we are concerned that AIR will be the starting point for the majority of patients. There will be a significant number of patients who are symptomatic and will require MART (regular) therapy starting first. We recommend this section is made clearer to ensure that if patients have had an exacerbation (not just severe) they are started on MART first to support correct use of MART and AIR. Furthermore, many patients do not relate certain symptoms as asthma, such as cough and will not necessarily use their ICS/LABA PRN for this.
20	Guideline	13	8	1.7.5 Consider linking the LTRA recommendation to MHRA advice on the risk of neuropsychiatric reactions https://www.gov.uk/drug-safety-update/montelukast-reminder-of-the-risk-of-neuropsychiatric-reactions
21	Guideline	13	19	1.7.7 This guideline makes no mention of using high-dose ICA/LABA inhalers. It would be useful to mention the limited place of high dose so that it is clear that the authors have specifically not increased

				the dose prior to referral (although patients may be on high dose through use of MART) Healthcare professionals may question what they should do to try to improve care for adult patients uncontrolled on moderate dose ICS, LABA, LTRA and a LAMA, besides referring to specialists in asthma care. Has the guideline committee considered? 1. Waiting times to specialist asthma clinics 2. Capacity of specialist asthma clinics and whether there is capacity for all to be referred at this step, even if appropriate to do so? 3. What should primary care do whilst waiting for first appointments at specialist asthma clinics? 4. The role of integrated care respiratory services?
22	Guideline	13-15	General	The recommendation to recommend single-inhaler therapy as either as needed low-dose ICS/formoterol or MART regimens in people aged 12 and over is to be commended. However as the sole recommendation, we have a number of concerns: 1. These regimens are not suitable for all people with asthma. In real world studies, such as the AstraZeneca sponsored SENTINEL project specifically designed to transfer people to MART regimens, only 44.7% transitioned to MART (Crooks MG, Crowther L, Cummings H, et al. Improving asthma care through implementation of the SENTINEL programme: findings from the pilot site. ERJ Open Res 2023; 9: 00685-2022 [DOI: 10.1183/23120541.00685-2022]). Clearly there are a significant number of patients not suitable for MART (e.g. patient preference, unable to understand the regimen, unable to self monitor etc). Consequently this guideline should also provide recommendations on fixed dose regimens. 2. Single-inhaler as needed low-dose ICS/formoterol or MART regimens must be supported with the provision of an appropriate asthma action plan to enable self-management. Unfortunately, the availability of these in languages other than English are limited, so may not be appropriate for non-English speakers. As of July 2024, Asthma+Lung UK have these available in only 9 languages (English, Arabic, Bengali, Chinese, Welsh, Gujarati, Polish, Punjabi, Urdu) https://www.asthmaandlung.org.uk/symptoms-tests-treatments/treatments/mart/download#download ; https://shop.asthmaandlung.org.uk/collections/air-action-plans
23	Guideline	13	8-18	1.7.5 and 1.7.6 – can we provide more guidance on “ineffective” and monitoring the outcome from the addition of 3 months of addition of LRTA and LAMA. We suggest an improvement in symptoms but not exacerbation frequency.
24	Guideline	13	19	1.7.7 ‘Refer people to a specialist in asthma care’ – there will be questions as to what the definition of a specialist is – we can understand keeping this broad so as not to restrict to/overwhelm certain sectors such as secondary care but it may be worth adding a comment to the effect of: ‘specialists maybe multiprofessional and also based in primary care and community settings’, especially as we move to more integrated models of care

25	Guideline	14	1-28	1.7.8 – 1.7.11 Transferring people from other treatment pathways The aim should be to step down treatment in people with well controlled asthma to the lowest dose possible and if changing prescriptions from ICS/LABA plus SABA to MART after assessment then this should be considered and included in these recommendations. (recommendation 1.10) Potential shortage issues of ICS/formoterol due to increased demand, if widespread adoption. Also possible inappropriate "switching" from ICS/LABA + SABA without training/ appropriate shared decision making, in patients who currently have well-controlled asthma
26	Guideline	14	4	1.7.8 We would like to see a stronger recommendation to change treatment from SABA to ICS/LABA rather than the current wording of "consider"
27	Guideline	15	1	1.7.12 Refer to specialist – see comment above for 1.7.7 as to what a specialist might be We agree that patients uncontrolled on high dose ICS should be referred if uncontrolled to a severe asthma clinic. Please provide recommendations for those that are controlled especially as high dose is not a recommendation in the treatment algorithm. For example these could align with the existing AAC uncontrolled asthma consensus pathway https://www.healthinnovationoxford.org/our-work/respiratory/asthma-biologics-toolkit/aac-consensus-pathway-for-management-of-uncontrolled-asthma-in-adults/
28	Guideline	22	6	1.14.4 In the context of MART is quadrupling the dose of ICS evidence based and relevant?
29	Guideline	23	2	1.15.1 Risk stratified care – this should also include 'overuse of MART therapy' which may suggest either suboptimal control or other issues including anxiety, breathing pattern dysfunction (further driven by overuse of betagonists generally) Please also consider including as a criteria here - short course oral corticosteroid use (including rescue packs)
30	Guidelines	23	7	1.16 Consideration should be given to prescribing of AIR and MART on primary care systems to ensure patients can order sufficient in line with their asthma symptoms but also are monitored to ensure that overuse of "reliever" ICS/LABA does not occur. Hybrid/virtual care models aside we should suggest here that the primary care reviews are done face to face and not via telephone to enable observation of inhaler technique as well as any other physical examination and objective testing
31	Equality impact assessment	General	General	No assessment made of the limited range of patient information and AIR and MART asthma action plans available in languages other than English. As of July 2024, Asthma+Lung UK have these available in only 9 languages (English, Arabic, Bengali, Chinese, Welsh, Gujarati, Polish, Punjabi, Urdu) https://www.asthmaandlung.org.uk/symptoms-tests-treatments/treatments/mart/download#download ; https://shop.asthmaandlung.org.uk/collections/air-action-plans
32	Supporting	General	General	This algorithm is hard to read. Healthcare professionals are more familiar with horizontal stepwise

	documentation: Algorithm (treatment)			algoithms used in the previous BTS/SIGN asthma guidelines and GINA guidelines. To improve implementation, a similar and more familiar algorithm may be more impactful to change practice.
33	Supporting documentation: Algorithm (treatment)	General	General	Consider reproducing the BTS/SIGN inhaler dose tables, to help readers understand what is a low and medium dose ICS/formoterol inhaler.
34	Supporting documentation: Algorithm (treatment)	3	General	For newly diagnosed and present as highly symptomatic or with severe exacerbations, low-dose MART is recommended. The pathway only then suggests an option for if asthma is controlled. However, it does not recommend dose escalation if uncontrolled, which would be to medium-dose MART
35	Supporting documentation: Algorithm (treatment)	1-3	General	The algorithms only flow in one direction - to step up treatment if asthma is uncontrolled. They should also include stepping down for those who are controlled as per section 1.10 p18-19.
36	Guideline	5	22	Is a blood eosinophil above the reference range always diagnostic of asthma? There are other conditions where eosinophils are elevated that are not asthma. Consider clarifying this to rule out other causes.
37	Guideline		General	Generally, there needs to be more explicit guidance throughout the document in terms of being SABA free. Whilst it is welcomed that there is a recommendation (1.6.2) suggesting no use of SABA without ICS there is nothing specific thereafter for patients who are on AIR or MART and this maybe misinterpreted by health staff. As a result there is a risk that patients may still get issued SABA alongside their ICS/LABA even though we are trying to move away from reliance on SABA and its inappropriate use. More directive advice required around SABA use for children, especially if on ICS/LABA as historically spare SABAs are kept in multiple locations such as schools or different household locations. This will also need consideration for wider NHSE work on asthma CYP ICS deliverables and 'asthma free schools' work stream, including teaching to support school staff in terms of organisation and delivery of care
38	Guideline		General	There is no real mention of acute severe asthma within guideline and suggest that there is some link to this/acute deteriorating asthma, especially how it might be initially managed in out of hospital settings and incorporated into PAAPs. With respect to the comment about SABA in row prior, it is also important to consider how a patient self manages in an emergency before getting to hospital/ambulance – usually current practice people can use up to 10 puffs of SABA via spacer in emergency if needed but if they don't have SABA they cant which implies to clinicians and patients they might need SABA just in case

				and negates AIR/MART only prescribing. Appropriated guidance on use of ICS/LABA in this situation should be provided.
39	Guideline		General	There need to be clearer cut offs for moving from AIR to MART regime. There should also be a suggestion on the number of days they are uncontrolled e.g. 3 days mentioned but this doesn't account for doses taken e.g a patient using maximal MART or greater for 2 days
40	Guideline		General	Pharmacological management section 1.7 – 1.10 there is no mention of shared decision making, this is only mentioned in the adherence section and suggest this is made more explicit in each section where a recommendation to prescribe or escalate/decrease therapy is made
41	Guideline		General	Section 1.7 – should specify for adults and children what constitutes low dose, moderate dose and high dose ICS (high >800-1000mcg Beclomethasone diproprionate equivalent in adults)
43	Algorithm treatment	Page 3	General	Adults - Right side box has criteria 'Asthma uncontrolled on SABA alone → offer low dose ics/Formoterol as needed' Suggest the 'uncontrolled on SABA alone' criteria is removed as no patients should be on SABA alone

Insert extra rows as needed

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