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Aerogen Ltd	General	General	Are there any cost saving interventions or examples of **innovative approaches** that should be considered for inclusion in this guideline? • Dunne et al. performed a chart review that compared standard hospital practice with a jet nebuliser, with the implementation of a vibrating mesh nebuliser. Compared to jet nebuliser's standard treatment group, the hospital admission rate of patients was lower for patients who received bronchodilator therapy via a vibrating mesh. In addition, the vibrating mesh nebuliser group was associated with more discharges from the emergency department and a shorter duration of stay in the emergency department[10]. • The use of a standard jet nebuliser in patients receiving high flow nasal cannula may require the discontinuation of respiratory support to release the nasal route, hence the reported use of a jet nebuliser with facemask over the nasal cannula in clinical practice. Reminiac et al. assessed bronchodilation with salbutamol in patients with reversible airflow obstruction (including asthma) with a vibrating mesh	Thank you for your comment. The developers are aware of jet nebulisers but there is insufficient evidence to include this as a topic in the scope. We will pass your comment to the NICE surveillance team so that they are aware of any evidence that is published in the future.

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			nebuliser inline through a high flow nasal cannula circuit, compared with a standard jet nebuliser and face mask. Salbutamol nebulisation with a vibrating mesh nebuliser induced similar bronchodilation, in terms of increase in FEV_1, to that observed with a standard jet nebuliser and face mask[11]. References: 10 Dunne RB, Shortt S. Comparison of bronchodilator administration with vibrating mesh nebulizer and standard jet nebulizer in the emergency department. *Am J Emerg Med* 2018; **4**: 641–646. 11 Reminiac F, Vecellio L, Bodet-Contentin L, Gissot V, Le Pennec D, Salmon Gandonnière C *et al.* Nasal high-flow bronchodilator nebulization: a randomized cross-over study. *Ann Intensive Care* 2018; **8**: 128.	
Aerogen Ltd	005	016	Diagnosis: The draft scope is reviewing evidence on diagnosis. Recent publications have reported the utilization of vibrating mesh nebulisers in methacholine challenge diagnostic tests for lung responsiveness[1,2]. • The European Respiratory Society guidelines for methacholine challenge testing recommend the	Thank you for your comment. The guideline committee will consider evidence that meets the review protocol criteria. We will make the committee aware of the references you have provided.

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			reporting of data as the PD20 (provocative dose of methacholine causing a 20% fall in FEV_1) instead of the PC20 (provocative concentration causing a 20% fall in FEV_1)[3]. PD20 values can only be calculated if the nebuliser used has been well characterized, particularly with regard to its output (i.e., dose delivery)[1].The standard jet nebuliser recommended in the American Thoracic Society guidelines for methacholine and exercise challenge testing has become difficult to obtain[1]. • In patients with mild asthma who completed four methacholine challenges, methacholine concentrations that caused a 20% fall in FEV_1 were significantly lower with a vibrating mesh nebuliser compared with a standard jet nebuliser[2]. References: 1 Blais CM, Cockcroft DW, Davis BE. Comparability of methacholine challenge test results between two jet nebulizers. *Can J Respir Crit Care, Sleep Med* 2018; **2**: 69–71. 2 Davis BE, Simonson SK, Blais CM, Cockcroft DW.	

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			Methacholine Challenge Testing. *Chest* 2017; **152**: 1251–1257.	
Aerogen Ltd	006	001	Management of Acute Asthma. We believe that management of acute asthma should be referred to in the Asthma Pathway guidelines, as recently published evidence on nebulisation efficacy has not been included to date. Improved clinical outcomes have been reported in patients who received bronchodilator therapy via a vibrating mesh nebuliser in both the emergency department and the intensive care unit[4–7] • In a randomised control trial of children with a known history of asthma who presented to the emergency department with an acute moderate to severe exacerbation, patients who received bronchodilator therapy had a lower probability of being admitted to the hospital, required significantly fewer treatments and less time to reach a mild asthma score compared with those in the jet nebuliser group[4].	Thank you for your comment. The recommendations in the BTS/SIGN guideline will not be included in update but recommendations will be maintained as part of a new 'asthma clinical pathway'

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			• In paediatric patients with critical asthma admitted to the intensive care unit who adhered to a protocol that included bronchodilator delivery using a vibrating mesh nebuliser, there were significant reductions in clinical outcome measures including time on continuous albuterol, paediatric intensive care unit stay length of stay and hospital length of stay[5]. • In paediatric patients with critical asthma admitted to the intensive care unit, bronchodilator delivery via a vibrating mesh nebuliser during high flow nasal cannula performed similarly to a large volume continuous nebuliser and aerosol mask[6]. • In a pilot randomised control trial of adults with acute asthma, there was a more rapid improvement observed in airflow through to time of disposition in patients who received bronchodilator therapy via a vibrating mesh nebuliser when compared with a jet nebuliser[7]. References: 3 Coates AL, Wanger J, Cockcroft DW, Culver BH, Carlsen KH, Diamant Z *et al.* ERS technical standard	

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			on bronchial challenge testing: General considerations and performance of methacholine challenge tests. *Eur Respir J* 2017; **49**: 1601526. 4 Moody GB, Luckett PM, Shockley CM, Huang R, Ari A. Clinical Efficacy of Vibrating Mesh and Jet Nebulizers With Different Interfaces in Pediatric Subjects With Asthma. *Respir Care* 2020; : respcare.07538. 5 Kucher NM, Dhaliwal DS, Fischer GA, Davey CS, Gupta S. Implementation of a Critical Asthma Protocol in a Pediatric ICU. *Respir Care* 2021; : respcare.07944. 6 Gates RM, Haynes KE, Rehder KJ, Zimmerman KO, Rotta AT, Miller AG. High-Flow Nasal Cannula in Pediatric Critical Asthma. *Respir Care* 2021; : respcare.08740. 7 Chweich H, Idrees N, Rice L, Rideout J, Barnewolt B, Kamlarz S *et al.* Effectiveness of a Vibrating Mesh Aerosolizer Compared to a Jet Nebulizer for the Delivery of Bronchodilator Therapy to Acute Adult Asthmatics in the Emergency Department a Randomized Controlled Trial. American Thoracic Society, 2019, pp A2209–A2209.	

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Aerogen Ltd	006	005	Environment. We believe that the environmental impact of inhaled therapies such a pressurised metered dose inhalers should be highlighted within the updated guidelines, with alternatives proposed. With growing concern about global warming, there is now a worldwide initiative to phase out the production of hydrofluoroalkanes (HFAs) that are used in pressurised metered dose inhalers and to find alternative compounds of low global warming potential[8]. Vibrating mesh nebulisers are electrically powered, applying energy to the vibrational element to move liquid drug through a micron mesh at a very high frequency to generate aerosols[9]. References: 8 Keeley D, Scullion JE, Usmani OS. Minimising the environmental impact of inhaled therapies: problems with policy on low carbon inhalers. *Eur Respir J* 2020; **55**. doi:10.1183/13993003.00048-2020. 9 Dhand R. How should aerosols be delivered during invasive mechanical ventilation? *Respir Care* 2017; **62**: 1343–1367.	Thank you for your comment. The importance of selecting the right inhaler device for each patient will be included in the guideline, and where devices are equally acceptable environmental factors will be taken into account. The developers intend to recruit an expert on environmental issues to support the committee.

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ALK-Albello (UK)	General	General	There is no emphasis on the use of licensed products with licensed indications being recommended only due to the results from clinical trials demonstrating both efficacy and safety.	Thank you for your comment. The guideline committee will consider whether a therapy is licensed when making recommendations.
ALK-Albello (UK)	General	General	There should be the inclusion of the ARIA guidelines for the allergic asthma patients.	Thank you for your comment. Guidance from other organisations may be included if they meet the criteria outlined in the methods manual https://www.nice.org.uk/process/pmg20/chapter/linking-to-other-guidance#guidance-from-other-developers
ALK-Albello (UK)	General	General	There is no mention from a sustainability perspective, the use of tablets for management of allergic asthma is a viable option. ACARIZAX® contains 0 plastic; the blisters made of aluminium and packaging is comprised of cardboard. There is no requirement of the patient and HCP to participate in any recycling scheme- again no mention of the environmental benefit for choosing a tablet over an inhaled device.	Thank you for your comment. The developers will consider environmental benefits of therapy when there are two or more equally effective alternatives.
ALK-Albello (UK)	General	General	There is no mention of the risk stratification between allergic asthma and allergic rhinitis, Allergic asthma is commonly associated with other atopic conditions. This is especially important because modern therapies often target specific	Thank you for your comment. Management of other atopic conditions is beyond the remit of the guideline.

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			allergens eg HDM in Acarizax or IgE in biologic treatments - this is not mentioned currently within the guidelines to look to investigate, test and treat for atopy.	
ALK-Albello (UK)	005	011	Pharmacological Management: There currently is no recommendation for sublingual immunotherapy within the scope. The results of the clinical trial MT-04 (NCT01433523) a multi-centre, asthma sparing, double blind, placebo controlled randomised clinical trial. Outcomes included reduction in time to moderate & severe exacerbations and was well tolerated in patients initiated on SLIT HDM therapy vs Placebo + standard of care. We also have recent real world studies published that confirmed the findings within the MT04.	Thank you for your comment. Sublingual immunotherapy is not recommended in the current BTS/SIGN guideline after a careful review of the evidence, and it has not been prioritised for inclusion in this update.
ALK-Albello (UK)	005	011	Pharmacological Management: There is no alignment to GINA guidelines 2021; option for controller options in step 3&4, for which the inclusion of SLIT is based on the outcomes of MT04.	Thank you for your comment. The scope of this guideline is primarily aimed at primary and secondary care. SLIT is typically used in tertiary care. BTS/SIGN guidance does not recommend use of SLIT.
ALK-Albello (UK)	005	011	Pharmacological Management: There is no alignment to the Irish College of General Practitioners guidelines updated 2020, "SLIT Sublingual immunotherapy (SLIT) is recommended as a potential therapeutic option in step 3 of the guidelines in adult patients with sub-optimally controlled asthma despite low to high-dose ICS, with allergic rhinitis who are	Thank you for your comment. The scope of this guideline is primarily aimed at primary and secondary care. SLIT is typically used in tertiary care. BTS/SIGN guidance does not recommend use of SLIT.

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			sensitised to house dust mite and have FEV1 >70%. House dust mite desensitisation can be considered in selected patients with uncontrolled asthma"	
ALK-Albello (UK)	005	011	Diagnosis: The draft scope does not include allergy testing either skin prick testing or specific IgE for suspected allergic asthma patients with sensitivity to aero allergens.	Thank you for your comment. The role of IgE measurement (total and specific) in children, and of eosinophils at all ages, is included in the scope.
ALK-Albello (UK)	005	011	Diagnosis: There is no set differential diagnosis for allergic asthma in primary care before a referral to a specialist unless patients are uncontrolled and require further investigation; currently suspected eosinophilic asthma requires blood tests and FeNO-testing	Thank you for your comment. The role of IgE measurement (total and specific) in children, and of eosinophils at all ages, is included in the scope.
Association of Paediatric Emergency Medicine (APEM)	General	General	APEM welcome the update and merging of available guidance and look forward to unified advice in this important area.	Thank you for your comment.
Association of Paediatric Emergency Medicine (APEM)	007	016	We appreciate that it is planned but wonder if it is a missed opportunity to not also review the evidence and standardise guidance on management of acute asthma as part of the update.	Thank you for your comment. Guidance on the management of Acute Asthma will be maintained by BTS/SIGN and signposted within the NICE guideline.

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Association of Paediatric Emergency Medicine (APEM)	007	017	Difficult or severe asthma: We wondered what the rationale was for not covering this area? Does this mean that it will not be included in the new guidance?	Thank you for your comment. Severe and difficult asthma is extremely important but it is managed by specialist groups across the UK, not by generalists, and is therefore not included in the scope. However, BTS & SIGN will maintain their guidance on this topic and the NICE guideline will signpost to this.
Asthma UK and the British Lung Foundation	General	General	As per the consultations call for any cost saving interventions or examples of innovative approaches that should be considered for inclusion in this guideline, we would like to share the NHS Accelerated Access Collaborative's review of FeNO, *The Economic Case for Fractional Exhaled Nitric Oxide (FeNO) in the Management of Asthma*, which is attached alongside this comment form.	Thank you for the information.
Asthma UK and the British Lung Foundation	General	General	The NHS is rapidly undergoing monumental change in response to the COVID-19 pandemic, and the joint guideline should take this into account. The increased utilisation of digital technologies including remote consultations is having a profound effect on the way the NHS provides care to patients which is transforming how health services are being delivered.	Thank you for your comment. NHS services are adapting to implement interventions as appropriate following national guidance and restrictions relating to COVID-19, with social distancing where appropriate. This is an evolving situation and so the recommendations will remain based on where evidence demonstrates interventions are clinically and cost effective. Implementation of these should take the current context into account.

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Asthma UK and the British Lung Foundation	General	General	We also concerned that the planned timelines are too long, and asthma care will have moved on again by the time the guidelines are published.	Thank you for your comment. There is always a tension between utilising new information and making sure that recommendations are based on sound evidence. H**owever, we recognise that this is a large guideline and will consider publishing recommendations in consecutive stages.** The literature searches are re-run towards the end of the development of the guideline to ensure that any evidence that meets the review protocol criteria published is included.
Asthma UK and the British Lung Foundation	005	General	We are disappointed that the scope of the joint guideline is so limited and lacks the ambition needed to improve asthma care to a standard of other European countries. We are concerned that the plan to form a broader set of guidance and materials, as opposed to one comprehensive guideline, will be confusing and not used. For instance, how will it be ensured that all parts of the guidance continue to be updated in accordance with each other so as not to become conflicting again? What will be the incentive for clinicians without a respiratory interest, who often treat people with asthma, to access different materials beyond the NICE guideline?	Thank you for your comment. Covering every aspect of asthma care would take a lot longer than the proposed timeline, and the developers note comments elsewhere (including from yourselves) asking that this should be shorter rather than longer. The scope therefore tries to address the areas of asthma care covered by non-specialists. Other topics will still be addressed by BTS/SIGN, and links to these will be contained within the NICE guideline. The NICE surveillance team will review the need to update the guidance based on the availability of new evidence.

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			We strongly urge NICE/BTS/SIGN to ensure the joint guideline also includes our recommendations outlined below.	
Asthma UK and the British Lung Foundation	005	General	As per current NICE guidelines, children with asthma cannot receive a formal diagnosis of their condition until they reach the age of five. Asthma UK has long been calling for children aged five or under with suspected asthma to have their status formally logged in GP records, so they don't fall off the radar. It would mean that they are more likely to receive appropriate treatment and management for their condition, with the necessary tests they need to confirm or rule out their asthma diagnosis as soon as they turn five. When NICE, BTS and SIGN update and unify current guidance on diagnosing asthma in young children, we believe this should include guidance recommending that children under five years of age with suspected asthma are coded, so their status is formally recorded and they can be followed up with appropriately, as soon as they turn five. This was a safety observation that was recently recommended by the Healthcare Safety Investigation Branch, following their investigation into the management of chronic asthma in children aged 16 years and under.	Thank you for raising this. In scoping the current version of this guideline, we also felt that there was a need to develop better guidance on the Under-5 group. We also acknowledge that healthcare professionals (primary, secondary, tertiary) would benefit from guidance on when to code "wheeziness" as "suspected asthma", to ensure they have better outcomes. This ethos is also part of the work of the National Asthma and COPD Audit programme (NACAP) CYP workstream, and the NHSE "Early and Accurate Diagnosis" working group. The evidence behind the recommendations for those groups will be formulated as part of the NICE/BTS guideline, and we think this will be an important and well-received addition.

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Asthma UK and the British Lung Foundation	005	General **SABA overuse/MART**	We are pleased to see that there will be a review of pharmacological management. It is important that the guideline considers the changing policy landscape on Delivering a 'Net Zero' National Health Service, and the importance of environmental factors in deciding what treatments to offer patients which need to continue being tailored to individual preferences, clinical need and patient outcomes. For example, NHS initiatives such as the Investment and Impact Fund will encourage the choice of lower carbon inhaler alternatives, where clinically appropriate. When reviewing current guidance on pharmacological management and the treatment pathway for adults, children and young people, we would also urge NICE, BTS and SIGN to review evidence on the use of short-acting β2 agonists (SABAs). It estimated that 20% of people with asthma do not receive treatment with inhaled corticosteroids (ICS), which means over a million people with asthma solely rely on a reliever inhaler for treating their asthma[i]. We know that many people with asthma don't take their preventer medication regularly and instead rely on their SABA reliever. Unlike a preventer	Thank you for your comment. The use of alternatives to SABA-only treatment in mild asthma, and of the MART strategy in mild/moderate asthma, are both included in the scope.

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			inhaler, SABAs do not treat the inflammation of the airways. SABAs only temporarily relieve symptoms by relaxing the airway muscles. SABAs treat asthma symptoms and can be life-saving, but preventer medication is needed to treat underlying inflammation and build up protection in the airway, helping prevent asthma symptoms and asthma attacks. In the National Review of Asthma Deaths (NRAD) which was published over seven years ago, there was evidence of excessive prescribing of reliever medication. Among 189 patients who were on short-acting relievers at the time of death, the number of prescriptions was known for 165, and 65 of these (39%) had been prescribed more than 12 short-acting reliever inhalers in the year before they died, while six (4%) had been prescribed more than 50 reliever inhalers.[ii] Unfortunately, little has changed in asthma outcomes since then. We now know that overuse of SABAs (just three or more inhalers a year) is linked to increased hospital admissions, asthma attacks and even deaths[iiiivvvivii]. Some studies have found that regular use of SABA, even for 1–2 weeks, is associated with adverse effects, such as reduced organ or	

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			cell activity, a narrowing of air passages in the lungs, increased allergic response to asthma triggers, and increased inflammation in the airway[viiiix]. In addition, the use of antidepressants, hypnotics and sedatives have been found to be greater in patients who overuse SABA suggesting an association with overuse of SABA and mental health problems[x].There is also some evidence to suggest that excessive use of SABA in people with severe asthma causes adverse lung changes and increases airway inflammation[xi]. Many studies have shown that when symptoms worsen, most people increase SABA use instead of using preventer medication. Some people are also known to stop using their preventer inhaler completely, in favour of only using their reliever when symptomatic. In our most recent Annual Asthma Survey, we found that 28% of respondents said they don't always take their preventer as prescribed and 1 in 10 said they only take it half the time or even less. An estimated 400,000 (7.4%) take their preventer less because they think their reliever inhaler is working.[xii] We know that when ICS is stopped, inflammation in the lungs is not being treated and this causes the risk of an asthma attack to increase by more than three times.[xiii]	

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			This behaviour might be attributed to several 'paradoxes' in current asthma management, which can be misleading to people about the relative importance of preventer and reliever medication. For example, NICE currently recommends SABA alone for those who have infrequent, short-lived wheeze and normal lung function, even though SABA does not treat the underlying inflammation. Every single day, people's lives are being put at risk because they are encouraged to treat their symptoms with SABA rather than the causes of those symptoms being addressed. People are not using their preventer medication which is needed to treat underlying inflammation and build up protection in the airways, helping prevent asthma symptoms and asthma attacks. Many people with asthma are unaware of the rationale behind the treatments that they are given, and many healthcare professionals do not adequately monitor or assess patients who appear to be overusing their reliever or underusing their preventer therapies.	

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			In fact, there is evidence to suggest that some people develop a complex behavioural relationship with their SABA.[xviii] This is demonstrated in the quotes below from qualitative research commissioned by Asthma UK. *"This is like my little miniature child. Like it's just part of who I am. It comes with me everywhere [describing reliever inhaler]."* *"Because the blue one [reliever inhaler] is going to save my life. The purple one is… I don't know, the preventer or whatever, so it prevents the attacks. The blue is the cure. It's like that's the holy grail of my life, the blue. The purple one, I don't really have the same attachment to it."* The UK is also an outlier compared to other European countries, with 38% of the asthma population using three or more SABAs in a year compared to just 9% in Italy, 16% in Germany and 30% in Sweden[xiv]. This mounting evidence has led to the Global Initiative for Asthma (GINA) changing their global guidelines to no longer include prescribing SABAs alone[xv]. However, UK guidelines	

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			including NICE and BTS/SIGN still recommend SABA alone in certain parts of the treatment pathway. The recent Investment and Impact Fund has set out incentives for primary care to increase the use of ICS prescribed for people with asthma, and reduce the amount of SABA prescribed. Current guidelines are therefore out of step with the changing policy and practice landscape for asthma. GINA now also recommends 'as needed' maintenance and reliever therapy (MART) as the preferred approach for mild asthma treatment, based on evidence that shows lower risk of severe exacerbations for people with similar symptom control compared with SABA alone.[xvi] The move to MART "as needed" seems to suit patient need as well, according to a Foster et al study on patient experience. It found that many believed MART "as needed" to be an acceptable reliever therapy that fitted well into their daily life, and that was easier to transition to than conventional daily preventer therapy[xvii]. Although a minority preferred their usual SABA treatment, it was suggested that individualised support from a healthcare professional may reassure them to make the transition. Furthermore, research from Fitzgerald et al found that from a UK healthcare payer	

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			perspective, as-needed MART is a cost-effective option for the treatment of mild asthma versus regular ICS[xviii]. We recommend NICE, BTS and SIGN to no longer recommend prescribing SABA as the only treatment for someone with asthma in their upcoming guideline, but always with ICS, either together as combination therapy or as separate inhalers. Given the evidence, we think NICE should consider the evidence behind using MART earlier in the treatment pathway and explore the evidence behind the effectiveness of using MART 'as needed' rather than solely as maintenance therapy.	
Asthma UK and the British Lung Foundation	006	General **Difficult/severe asthma** **OCS use**	We are extremely disappointed to see that difficult/severe asthma has not been included within the scope of the NICE/BTS/SIGN joint guideline. Of the 5.4 million people in the UK living with asthma[xix], around 1 million have 'difficult' asthma which includes an estimated ~200,000 people in the UK with 'severe' asthma, a condition that needs specialist assessment and bespoke support and treatments[xx]. Without specialist treatment and support, people with asthma can be given and remain on the wrong treatment and even potentially the wrong diagnosis altogether, putting them in a never-ending cycle of emergency trips to hospital and toxic	Thank you for your comment. Severe and difficult asthma is extremely important but it is managed by specialist groups across the UK, not by generalists, and is therefore not included in the scope. However, BTS & SIGN will maintain their guidance on this topic and the NICE guideline will signpost to this. The developers agree that oral steroid use should be avoided as much as is possible and acknowledge the role of biologic treatments. They are not included in this update for the same reasons as Severe and difficult asthma, and

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			oral steroids[xxi]. Currently there are no comprehensive NICE guidelines for difficult/severe asthma and no clear referral criteria. Treatment and care for severe asthma has transformed over the last few years. There are now dedicated specialist services which offer a comprehensive systematic assessment, multidisciplinary team input and phenotyping. Non-pharmacological support is also important for this group of people and we are disappointed not to see this included within the scope either. There are now five life-changing biologic treatments available in England, Wales, Northern Ireland, and Scotland, but we know access to these is poor. Our report 'Do no harm: better and safer treatment options for people with asthma' showed that an estimated 46,000 people who are potentially eligible for these treatments are still missing out. People are unable to access specialist services because there is a lack of awareness that severe asthma is a distinct condition that has dedicated services and biologic therapies to treat it effectively. Health professionals do not know when to refer someone or understand the benefits that a referral to a specialist could bring. Consequently 82% of	because they are already covered by NICE Technology Appraisals. Advice on referral will be offered in the guideline update and we have added this to the Scope.

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			people who would benefit from seeing a specialist according to BTS guidelines, don't get referred[xxii]. Our other research has also shown that there is variation in when clinicians think they should refer. This is because current guidelines are confusing and conflicting[xxiii]. It is crucial that guidelines are not only aligned on what referral criteria should be, but that clear referral criteria are also included within NICE guidelines. This is because most people with asthma are treated within primary care and may not ever see a clinician with a specialist interest in respiratory who would consult guidelines other than NICE. A developmental NICE Quality Standard for suspected severe asthma exists and provides a definition of severe asthma but does not go far enough. It is incomprehensible that a condition affecting ~200,000 people in the UK did not have a NICE management guideline until the COVID-19 pandemic when rapid guidance was produced. This was a positive step, but a fully evidenced guideline with clear referral criteria is still urgently needed to address the huge unmet need and show the benefits of referring someone to specialist care.	

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			Unless referred to specialist care, people with difficult/severe asthma are often forced to take toxic high dose oral steroids which have life-limiting side effects including osteoporosis, diabetes, weight gain and insomnia. It has now been shown that just four courses of oral steroids over a lifetime are associated with adverse effects[xxiv]. Our recent survey of over 2,000 people who had used oral steroids in the last year revealed the devastating consequences of oral steroids on quality of life, with 73% experiencing at least one side effect and a third experiencing side effects relating to their mental health. Of those surveyed, 24% said they make them feel less confident and one in five said they make it difficult to do everyday tasks.[xxv] The hidden mental toll of oral steroid side effects needs urgent addressing, but current NICE guidelines do not do enough to equip clinicians on how to limit oral steroid use or give them clear information as to when someone should be referred. Guidance for primary care on how to treat 'difficult' asthma or those requiring oral steroids exists, such as the SIMPLES approach, but this is not currently included within national guidelines. We urge NICE to consider more comprehensive recommendations such as systematic assessment, which	

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			includes non-pharmacological treatment approaches such as lifestyle advice. Future guidelines also need to promote a greater clinical intolerance to poor asthma control by including recommendations on robust follow-up, assessment and referral of people with poor asthma control and reliever use, and people having asthma attacks or requiring oral steroids. Guidelines could play a key role in reducing reliance on oral steroids, but currently asthma lags behind other conditions which have more comprehensive guidelines. Great strides have been made in other disease areas such as rheumatoid arthritis and Crohn's disease in reducing the use of oral steroids. This is due to earlier and more preventative use of biologic treatments and a crucial shift in the focus of guidelines towards limiting oral steroids exposure and using them only as a last resort. There is an urgent need for a permanent, comprehensive and system-wide NICE difficult/severe asthma guideline to shift the thinking away from oral steroids as the only treatment option and to ensure primary and secondary care	

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			clinicians can confidently recognise and refer people with suspected severe asthma. Given the scale of this unmet need, we would urge NICE, BTS and SIGN to include severe and difficult asthma in the joint asthma guideline. There needs to be clearer guidance on identifying, assessing and referring people who may have difficult or severe asthma. This should be based on routine reviews in primary care and also triggered by data on prescriptions (SABA, OCS), unscheduled care (out of hours, A+E, admission) and can be coordinated at practice or system level.	
Asthma UK and the British Lung Foundation	006	General	Since the COVID-19 pandemic, clinicians have struggled to risk stratify patients most in need of care. Data should be readily available for clinicians to be able to identify patients with poor asthma control (e.g., SABA use, OCS prescribing, unscheduled care, symptoms etc.), highlighting poor adherence to preventer medicines. Data can be used to flag patients requiring support to the clinical team and form part of routine and ongoing monitoring.	Thank you for your comment. Coding issues are beyond the remit of NICE guidelines.

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			The joint guideline should consider including guidance for the NHS on coding, recording data and searching for high risk patients.	
Asthma UK and the British Lung Foundation	006	General	We welcome the review and alignment around diagnosis as this has caused much confusion. However, NICE, BTS and SIGN need to ensure that the new guidelines cover the role of diagnostic hubs, which were recommended by Professor Sir Mike Richards' recent review of NHS diagnostics capacity[xxvi]. This will be an essential component for getting the care of people with a lung condition back to normal and help overcome the diagnosis backlog, enabling patients to access early treatments so they can keep themselves well and not end up on inappropriate and costly medications[xxvii]. Existing NICE asthma guidance currently calls for asthma diagnostic hubs, but current practice suggests that Integrated Care Systems are moving towards a Community Diagnostic Hub model for respiratory diagnoses. As a result, some regions will be creating local hubs at a Primary Care Network level, allowing patients to access diagnostic tests such as Spirometry and Fractional Exhaled Nitric Oxide (FeNO) in an area local to them.	Thank you for your comment. The current NICE guideline proposes the use of diagnostic hubs, and indeed was one of the first national documents to advocate this. However, the developers do not think there is sufficient formal data on their efficacy to warrant an evidence review for this version of the guideline.

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			Alignment is needed on the recommendations for diagnostic hubs, based on what works best for patients, with the aim of improving access to diagnostic tests. We therefore recommend that NICE, BTS and SIGN undertake an evidence review into the role of diagnostic hubs as well.	
Asthma UK and the British Lung Foundation	007	008 - 011	Whilst we're supportive of the new asthma clinical pathway, it must take into consideration the incoming pre-diagnosis breathlessness pathway that's being developed by NHS England to ensure these pathways align and are condition agnostic. It is crucial that the guideline acknowledges how common and non-specific respiratory symptoms are. By having diagnostic guidelines for asthma, the clinician has already decided this is the most likely diagnosis. Clinical assessment needs to be more condition agnostic to aid clinicians and generalists by minimising bias and reducing inaccurate diagnosis. Common features of asthma are airway obstruction and airway inflammation. Having a measurement of both is essential in understanding a person's type of asthma and is likely to increase the proportion of accurate diagnoses. It will	Thank you for your comment. The developers recognise the importance of an assessment of breathlessness and its relationship to the current guideline. Since this is an asthma guideline, the Diagnosis section will assume as its starting point that the presenting symptoms have indicated the possibility of asthma as the cause.

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			also give the clinical team a potential steer on treatment choices, need for referral for specialist input and more evidence when discussing care with patients and colleagues. The joint guideline should consider the evidence around routinely carrying out measurements of airway obstruction and inflammation. Furthermore, the guidelines need to align with other conditions where symptoms overlap (e.g., COPD).	
Asthma UK and the British Lung Foundation	007	016	We also think acute asthma should be included within the joint guideline. Although this is covered well within the BTS guideline, the same concern exists that many people with asthma may be treated by clinicians who do not consult BTS guidelines but only NICE. As explained above, too many people are prescribed oral steroids without the appropriate care and follow-up needed to prevent future asthma attacks. There is currently a disconnect between 'routine' asthma treatment and acute situations. Poorly controlled asthma should trigger a pathway of care that is personalised, holistic and ends only when good control can be proven. Continuing to have separate guidelines for 'routine' and 'acute' will only make this less likely to happen and disadvantage people with asthma. The impact of this is	Thank you for your comment. The developers agree that Acute asthma is covered well within the BTS/SIGN guideline. This will be maintained by BTS/SIGN and signposted within the NICE guideline.

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			also demonstrated by the fact asthma deaths have risen over the last decade and we have not seen an improvement in asthma outcomes for years.	
AstraZeneca	General	General	**References** 1. Global Initiative for Asthma. 2021 GINA Report, Global Strategy for Asthma Management and Prevention. Available from: www.ginasthma.org/reports. 2. O'Byrne PM, FitzGerald JM, Bateman ED, et al. Inhaled combined budesonide–formoterol as needed in mild asthma. N Engl J Med 2018;378:1865-76. 3. Bateman ED, Reddel HK, O'Byrne P, et al. As-needed budesonide–formoterol versus maintenance budesonide in mild asthma. N Engl J Med 2018;378:1877-87. 4. Beasley R, Holliday M, Reddel HK, et al. Controlled trial of budesonide-formoterol as needed for mild asthma. N Engl J Med 2019;380:2020-30. 5. O'Byrne PM, FitzGerald JM, Bateman ED, et al. Effect of a single day of increased as-needed budesonide–formoterol use on short-term risk of	Thank you for the references. They will be considered when the relevant evidence is identified if they meet the review protocol criteria.

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			21. Bleecker, ER, FitzGerald JM, Chanez P, et al. Efficacy and safety of benralizumab for patients with severe asthma uncontrolled with high-dosage inhaled corticosteroids and long-acting β_2-agonists (SIROCCO): a randomised, multicentre, placebo-controlled phase 3 trial. Lancet 2016;388(10056):2115-27. 22. FitzGerald JM, Bleecker ER, Nair P, et al. Benralizumab, an anti-interleukin-5 receptor α monoclonal antibody, as add-on treatment for patients with severe, uncontrolled, eosinophilic asthma (CALIMA): a randomised, double-blind, placebo-controlled phase 3 trial. Lancet 2016;388(10056):2128-41. 23. Nair P, Wenzel S, Rabe K, et al. Oral glucocorticoid-sparing effect of benralizumab in severe asthma. N Engl J Med 2017;376(25):2448-58. 24. Jackson, D. Real-world clinical outcomes for patients with severe, atopic eosinophilic asthma treated with benralizumab in the UK. Presented at EAACI 2020, London. 25. Jackson DJ, Butler C, Chaudhuri R, et al. Recommendations following a modified UK-Delphi	

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			consensus study on best practice for referral and management of severe asthma. BMJ Open 2021; In press 26. NICE. Benralizumab for treating severe eosinophilic asthma [TA565], 2019. Available from: https://www.nice.org.uk/guidance/ta565 27. Rogliani P, Calzetta L, Matera MG, et al. Severe asthma and biological therapy: When, which, and for whom. Pulm Ther 2020;6:47-66. 28. Pavord I, Bahmer T, Braido F, et al. Severe T2-high asthma in the biologics era: European experts' opinion. Eur Respir Rev 2019;28:190054.	
AstraZeneca	003 004 004	024 017 – 018 024	**Severe asthma pathway and management should be in scope to ensure future clinical pathways, including treatment settings, are set up for best clinical outcomes for patients with asthma across the UK** This guideline document mentions under its scope all settings where NHS funded care is provided (page 4, line 24), covering groups of "adults, young people and children who are being investigated for suspected asthma, or who have been diagnosed with asthma" (page 4, line 17-18). Within that scope there is no specification with regard to the	Thank you for your comment. Severe and difficult asthma is extremely important but it is managed by specialist groups across the UK, not by generalists, and is therefore not included in the scope. However, BTS & SIGN will maintain their guidance on this topic and the NICE guideline will link to this.

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			severity of the disease, **therefore severe asthma should be part of the scope**. The setting in scope of this guideline includes primary, **secondary and tertiary care** (page 3, line 24), the latter being a setting where patients suffering from severe asthma are usually identified in, referred to and treated. However, a recent study showed that the majority of patients with potential severe asthma (72%) had not been reviewed by or referred to a specialist in the past year.[13] This is another reason why AZ would propose that severe asthma pathway and management should be included in the scope of this guideline.	
AstraZeneca	007	012 – 019	**Severe asthma pathway and management should be in scope to ensure UK wide consistency and integration of guidelines building on previous best practices** This draft scope for consultation excludes the following from the guideline update: • Biologics • Management of acute asthma • Difficult or severe asthma • Phenotyping (currently relevant only in severe asthma)	Thank you for your comment. Severe and difficult asthma is extremely important but it is managed by specialist groups across the UK, not by generalists, and is therefore not included in the scope. However, BTS & SIGN will maintain their guidance on this topic and will address definitions and distinctions as appropriate. The NICE guideline will signpost to BTS/SIGN guidance

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			When NICE scoped the guideline on asthma NG80, published in 2017, the use of biologics in severe asthma was limited, which may have been the reason why biologic therapies were not included in that guideline.[10] Since then, NICE has produced multiples TAGs, following STAs for biologics used in severe asthma. SIGN158, published in 2019, included severe and acute asthma, and biologic treatments of severe asthma.[11] NG166 COVID-19 rapid guideline: severe asthma (currently not included in the scope of this guideline), published in 2020, also specifically includes biologics as part of the therapies for the treatment of severe asthma.[12] However, this guideline was developed using the interim process and methods for guidelines developed in response to health and social care emergencies, and is only a temporary measure;[12] hence, biologic treatment for severe asthma should be included in the current draft scope. A primary need for this updated guideline from the clinical community is to integrate multiple, overlapping, confusing	

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			and fragmented-in-application guidelines. This, therefore, needs to build on both currently in-scope NICE NG80, BTS/SIGN 158, and currently out-of-scope NG166 and multiple TAGs for severe asthma treatments. This must be reflected in the final scope of this guideline update.	
AstraZeneca	007	014	**Severe asthma pathway and management should be in scope to ensure patients with asthma across the UK are able to easily access safe, effective, licenced, and reimbursed latest therapies** This draft scope for consultation excludes biologics from the guideline update. Currently, patients with severe asthma are often treated with maintenance OCS to avoid exacerbations that would require hospitalisation; however, these courses of OCS are associated with a range of adverse effects, including weight gain, bone weakening and fractures, cardiovascular disease (heart attacks and strokes), eye problems and mood changes.[20] Chronic use of OCS is largely unnecessary and potentially harmful when suitable biologic options exist. For example, the monoclonal antibody benralizumab reduces the annual	Thank you for your comment. Severe and difficult asthma is extremely important but it is managed by specialist groups across the UK, not by generalists, and is therefore not included in the scope. However, BTS & SIGN will maintain their guidance on this topic and the NICE guideline will signpost to this. The developers agree that oral steroid use should be avoided as much as is possible and acknowledge the role of biologic treatments. They are not included in this update for the same reasons as Severe and difficult asthma, and because they are already covered by NICE Technology Appraisals. Links to these will be included in the guideline.

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			rate of severe exacerbations by up to 70% versus placebo,[21-23] as well as substantially reducing OCS use and improving patient-reported outcomes.[24] Despite the availability of biologics, only a small proportion of eligible severe asthma patients have access to them, with the majority of severe asthma patients not referred to specialist care and sub-optimally managed with chronic OCS.[13,14] Patients with severe asthma currently require systematic assessment within a specialist multi-disciplinary secondary or tertiary care setting (settings included in the scope of this guideline) in which advanced therapies such as biologic treatments can be initiated if appropriate.[25] Such a restrictive pathway needs to be improved to achieve our collective aims of better clinical outcomes for patients with asthma of any severity across the UK. We again strongly recommend that the scope of this guideline should include severe asthma pathway and biologic therapies.	
AstraZeneca	007	017	**Severe asthma pathway and management should be in scope to ensure that NHS across the UK mitigates the significant economic burden of sub-optimal treatment for such patients**	Thank you for your comment. Severe and difficult asthma is extremely important but it is managed by specialist groups across the UK, not by generalists, and is therefore not included in the scope. However, BTS & SIGN will

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			It is estimated that there are 200,000 people in the UK with severe asthma that is difficult to control with standard treatments.[14] Such patients experience recurrent symptoms, impaired lung function, frequent exacerbations and high exposure to systemic corticosteroids (SCS).[15] Patients with severe asthma also have an increased risk of mortality compared with patients with controlled asthma. Several opportunities in clinical practice and pathway have been identified where improved care could reduce this, including better identification of risk status, and referral to a specialist when indicated.[16] Patients with severe asthma often have to wait for specialist treatment, and reasons for delays include inconsistent thresholds for referral from primary and secondary care and a lack of clarity on referral criteria.[17] Therefore, the inclusion of severe asthma pathway in the scope of this guideline could help provide a consensus for the effective and timely management of patients with severe asthma, and ultimately improve outcomes for those patients.	maintain their guidance on this topic and the NICE guideline will signpost to this.

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			Severe asthma is also associated with a significant economic burden, due to the high medication costs and costs associated with unscheduled healthcare utilisation and management of side effects related to treatment with oral corticosteroids (OCS).[1] These costs are four-fold higher in severe asthma than those for the general asthma population,[18] and one study found that severe uncontrolled asthma accounted for over 60% of total asthma costs.[19] Consequently, joined-up guideline is needed on the optimal pathway and management for these patients. For the above mentioned reasons, we strongly advocate that the scope of this guideline should include pathways and therapies for the treatment of difficult and severe asthma.	
AstraZeneca	007	019	**Many, though not all, new therapeutic approaches to asthma rely on phenotyping - therefore making it important to include in the scope of this guideline** This draft scope for consultation does not currently include phenotyping (relevant only in severe asthma). Patients with severe disease currently require systematic assessment including accurate phenotyping to assess their	Thank-you for your comment. Your arguments for phenotyping are all based on its role in severe asthma, but the guideline will not cover the management of severe asthma.

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			suitability for treatment.[25] The identification of different asthma phenotypes in recent years has led to the availability of innovative therapies, and identifying therapeutic biomarkers that characterise specific phenotypes could enable therapeutic strategies to be specifically tailored to individual patients' needs.[27] It is likely that phenotype identification will have a major impact on the pathway and management of severe asthma in the future. There is also a need to better understand the clinical relevance of phenotypes and biomarkers, and how they can be best utilised to identify suitable patients and improve asthma control earlier in the referral pathway.[28] Therefore, we suggest that the scope of this guideline should include phenotyping, in order to provide clearer guidance on this important component of severe asthma pathway and management.	
AstraZeneca	011	012 – 016	**Scope for ICS/LABA inhaler pathways in treatment-naïve patients is in line with most recent guidelines – AZ welcome this**	Thank you for your comment.

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			We welcome and support the inclusion of inhaled corticosteroid (ICS)/long-acting beta-agonist (LABA) inhaler prn in this guideline for the management of asthma in people who are treatment-naïve. Indeed, this is in line with the 2021 Global Initiative for Asthma (GINA) report and several other studies recommending low-dose combination ICS-formoterol as the preferred reliever for all severities of asthma, due to the reduced risk of exacerbations versus short-acting beta-agonist (SABA) reliever alone.[1-6] Also, an analysis conducted from a UK healthcare payer perspective found that as-needed budesonide-formoterol was a cost-effective treatment option versus maintenance low-dose ICS plus as-needed SABA for patients with mild asthma.[7]	
AstraZeneca	011	017 – 025	**Scope for ICS/LABA inhaler used as MART is also in line with most recent guidelines – AZ welcome this** We also support the inclusion of ICS plus LABA used as maintenance and reliever therapy (MART) in this guideline	Thank you for your comment. Your references will be considered when identifying the evidence that meets the review protocol criteria for this question.

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			for the management of asthma when initial management fails to provide adequate control. GINA recommends the use of ICS-formoterol MART as controller and preferred reliever in Steps 3–5 (moderate to severe asthma), due to the reduced risk of severe exacerbations versus regimens with SABA alone as reliever.[1] This recommendation is supported by two recent large scale reviews. Sobieraj et al. conducted a systematic review and meta-analysis of the effects of MART versus ICS ± LABA as controller plus SABA as reliever in over 22,000 patients aged ≥4 years with persistent asthma. The authors concluded that the MART regimen was associated with a significantly lower risk of asthma exacerbations.[8] Another systematic review and network meta-analysis by Rogliani et al. assessed over 32,000 adult patients with mild to severe asthma and found that low- to medium-dose MART was similarly effective to high-dose ICS/LABA plus as-needed SABA in reducing severe asthma exacerbation risk.[9] The MART regimen was also significantly more effective than lower doses of ICS/LABA plus as-needed LABA or SABA, as-needed ICS/LABA, or ICS plus as-needed SABA.	

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Chiesi Limited UK	General	General	**We support the development of the joint guidelines between NICE and BTS/SIGN. We would also welcome the consideration of the evidence used to inform the development of the recommendations included within the most GINA guidelines[1], which is already being embedded into clinical practice. This evidence takes into account the challenges related to SABA overuse. In particular, the recent SABINA study is worthy of note, which highlights that the UK has one of the highest rates of SABA overuse in Europe, which is linked to poor asthma outcomes.[2]** [1]Global Initiative for Asthma (GINA) Full Report 2021 [2] Janson C et al. Adv Ther. 2020; 37(3): 1124–1135	Thank you for your comment. The clinical and cost effectiveness of SABA and of alternatives to SABA is included in the scope of the guideline (draft review questions 3.1 and 3.2). Guidance from other organisations may be included if they meet the criteria outlined in the methods manual https://www.nice.org.uk/process/pmg20/chapter/linking-to-other-guidance#guidance-from-other-developers
Chiesi Limited UK	006		**We ask for a reconsideration to review up-to-date evidence regarding inhaler devices and the impact to the environment. This is a fast-moving area of innovation, with the introduction of many carbon minimal propellants within pressurised metered dose inhalers (pMDI) from 2025.[1] The range of available DPIs on the marketplace has also significantly evolved since**	Thank you for your comment. The importance of selecting the right inhaler device for each patient will be included in the guideline, and where devices are equally acceptable environmental factors will be taken into account. The developers intend to recruit an expert on environmental issues to support the committee.

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			the last evidence review, which should also be taken into account in the updated guidelines. **We believe it is important to consider these new innovations when developing the updated guideline to ensure that both the pMDI and DPI platform are maintained for patient/prescriber choice as well as to allow the right device to be prescribed for the right patient, allowing optimal patient care and asthma management.** **[1]Pritchard J et al. Drug Des Devel Ther. 2020; 14: 3043–3055**	
Chiesi Limited UK	006		**We ask for a reconsideration to review up-to-date evidence regarding decreasing maintenance therapy in patients with asthma. Over the past few years there has been a lot of interest in this area that should be taken into account within the updated guideline.[1]** **[1]Rogers L et al. J Allergy Clin Immunol Pract. Mar-Apr 2018;6(2):633-643.e1**	Thank you for your comment. Recommendations on stepping down treatment are included in existing NICE and BTS/SIGN guidelines, and reworded versions of these will be included in this update. However, the developers have not been made aware of significant new evidence and this topic has not been prioritised for evidence review. It is noted that the study you quote did not show a significant difference between the two strategies it tested.

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Chiesi Limited UK	007		**We ask for a reconsideration to review up-to-date evidence regarding difficult/severe asthma with the introduction of a triple therapy combination inhaler on the market,[1,2] and to evaluate these treatment options in the prospective guideline.** **[1]Trimbow 87 micrograms/5 micrograms/9 micrograms pressurised inhalation solution, Summary of Product Characteristics, Chiesi Limited** **[2]Enerzair Breezhaler, Summary of Product Characteristics, Novartis Pharmaceuticals UK**	Thank you for your comment. Severe and difficult asthma is extremely important but it is managed by specialist groups across the UK, not by generalists, and is therefore not included in the scope. However, BTS & SIGN will maintain their guidance on this topic and the NICE guideline will signpost to this.
Chiesi Limited UK	009 - 010		**We ask for inclusion of a research question to consider evidence for tests to diagnose small airway dysfunction in the earlier stages of asthma, such as the use of impulse oscillometry. Detection of airflow limitation in this circumstance is insensitive to current spirometry assessments.[1]** **[1]Chiu HY et al. J Allergy Clin Immunol Pract. 2020 Jan;8(1):229-235.e**	Thank you for your comment. Impulse oscillometry is not available to most clinicians assessing possible asthma at presentation, and not routinely used even in specialist centres. It would be premature to include it in this version of the guideline.

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Chiesi Limited UK	011	012 - 016	**We support the inclusion of ICS/formoterol PRN at the initial stages of treatment for patients who are treatment-naïve. This would provide broad alignment with the GINA guidelines[3] which is starting to become embedded in clinical practice. The evidence to support this consideration is set out below:** • There is a growing body of evidence supporting the use of ICS-formoterol as a reliever, due to the formoterol component having a similar onset of action relative to salbutamol. which provides fast onset symptom relief.[1,9,10] • The NRAD (National Review of Asthma Deaths) report[2] highlighted the issues of SABA overuse, the report states there was evidence of excessive prescribing of reliever medication with 39% of patients out of 165 patients being prescribed more than 12 reliever inhalers in the year before they died. Further studies conclude that high SABA inhaler use is significantly associated with an increased risk of exacerbations which can be attributed for the ability of SABA inhalers to mask symptoms and mask worsening disease control.[4]	Thank you for your comment. Your references will be considered when identifying the evidence that meets the review protocol criteria for this question.

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			• The introduction of ICS-formoterol PRN is supported by the reduction in the risk of severe exacerbations following this regime when compared to SABA alone.[5] Furthermore, patients with infrequent asthma symptoms may still have exacerbations in which the ICS component is necessary to reduce underlying inflammation.[6] The recent SABINA study encapsulates these issues, and defines SABA overuse as more than 3 canisters of reliever medication per year.[7] • There is recognition that patients with mild and infrequent symptoms of asthma who are prescribed regular ICS would suffer with adherence and expose them to the risk of over-reliance of SABA inhalers if they are prescribed ICS + SABA.[8] Thus we support the use of ICS-formoterol PRN over ICS regular + SABA which would address such adherence concerns whilst meeting the needs to treat the underlying inflammation. [1] Noord J A Van et al. Respir Med. 1998 Dec; 92(12): 1346-51	

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			[2] Why Asthma Still Kills. The National Review of Asthma Deaths (NRAD) Report 2014 [3] Global Initiative for Asthma (GINA) Full Report 2021 [4] Bloom C et al. Adv Ther. 2020 Oct;37 (10): 4190-4208 [5] Beasley R et al. N Eng J Med 2019;380: 2020-30 [6] Nwaru B et al. Eur Respir J 2020; 55: 1901872 [7] Janson C et al. Adv Ther. 2020; 37(3): 1124–1135 [8] Barnes CB et al. Respir Care 2015;60 [9] O'Byrne P et al. N Engl J Med 2018; 378:1865-1876 [10] Bateman E et al. N Engl J Med. 2018; 378: 1877-1887	
Chiesi Limited UK	011	017 - 025	**We support the inclusion of ICS/LABA MART as a treatment option for those who require a step up in therapy when initial management fails. The key data supporting this approach is summarised below, as well as in the current GINA guidelines.[5]** • There is concern for the implications of polypharmacy and the prescribing of additional/separate therapies compared to increasing/optimising the dosages of current treatments.[1] This is further compounded by the negative impact of prescribing multiple inhalers or	Thank you for your comment. Your references will be considered when identifying the evidence that meets the review protocol criteria for this question.

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			different devices compared to single combination devices.[2] The consideration for ICS-formoterol (MART) at this treatment stage, allows patients to remain on the same treatment at Step 1. • There is evidence which supports the use of ICS-formoterol MART compared to ICS/LABA + SABA, with the findings demonstrating a significant reduction in the rate of severe exacerbation rates, significant reductions for emergency/hospital admissions and significant reductions in the use of systemic corticosteroids for more than 3 days. [3] • The inclusion of ICS-formoterol (MART) allows a continuous progression from ICS-formoterol PRN at step 1 with minimal disruption to changes in therapy whilst changing the way a patient would take the same inhaler. The use of MART allows patients to identify triggers and worsening symptoms in order to proportionately increase the dose of ICS to treat the escalating underlying inflammation as appropriate.[4]	

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			[1] Restrepo R et al. Int J Chron Obstruct Pulmon Dis. 2008 Sep; 3(3): 371–384 [2] Zhang S et al. Int J Chron Obstruct Pulmon Dis. 2020; 15: 417–438 [3] Papi A et al. Lancet Respir Med 2013; 1: 23–31 [4] Papi A et al. Allergy Asthma Clin Immunol 16, 75 (2020) [5] Global Initiative for Asthma (GINA) Full Report 2021	
Neonatal & Paediatric Pharmacists Group (NPPG)	General	General	As an organisation we are happy with the scope for this guideline.	Thank you for your comment.
NHS County Durham CCG	General	General	We are very pleased to see this collaborative guideline going ahead. However, it should include both acute and difficult to manage asthma as the sections in SIGN/ BTS guidance on these areas interact with the sections on chronic asthma management. Updating pathways alone may potentially lead to conflicting guideline statements?	Thank you for your comment. Guidelines on management of Severe asthma and management of Acute asthma will be maintained by BTS & SIGN, and the NICE guideline will refer to these
NHS England and Improvement - CYP Transformation Team -	General	General	Unfortunately, in my view, this update only due in 2023, which will still result in two separate UK guidelines for asthma will not address the key issues related to poor asthma outcomes in the UK, particularly disjointed management where quality of patient's care is subject to a postcode lottery, unacceptably high rates of admissions	Thank you for your comment. We agree that there are problems in the delivery of asthma care and that there are important and useful recommendations for improvement from various sources which have not been implemented.

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Asthma Oversight Group			poor quality of life, preventable deaths due to asthma, the process of asthma care, the lack of appropriately trained personnel the care across the interface, and particularly dealing with the particular problems patients experience due to a lack of joined up thinking and approach.	
NHS England and Improvement - CYP Transformation Team - Asthma Oversight Group	General	General	Working jointly is a big step forwards The narrow list of questions with respect to treatment and omission of adherence as a topic is a missed opportunity. Despite the fact that guidance was issued by NICE in 2002 about inhaler devices for children there appears no attempt to revisit this important area. There are 3 components to delivery of any successful inhaled therapy prescription (and most asthma treatments are of course inhaled). 1. The drug (which some effort will be made on... For treatment naive patients) 2. The inhaler type (really important for children as the type of device that can and will be used varies over time)	Thank you for your comment. We are aware of little new evidence on adherence that would impact on the current recommendations but these will be editorially refreshed and aligned. However, we have added a review question on clinical and cost effectiveness of smart inhalers.

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			3. The education Only tackling the drug question.. Rather than the device and whether it can be used (and is being used) seems like a missed opportunity.	
NHS England and Improvement - CYP Transformation Team - Asthma Oversight Group	General	General	The key problems related to asthma care and the comparatively bad UK asthma outcomes worldwide have not been addressed by this scoping document. These relate to quality and consistency of care within primary and secondary sectors as well as the interface between these and the tertiary care sector. The issues have been detailed in a number of UK reports of note the NRAD (2014), the APPG report (2020), the HSIB report (2021), the NACAP results as well as in the HM Coroners Regulation 28 reports on Ella, Kissi-Debra,Tamara Mills, Michael Uriely, Sophie Holman and countless others (published on HM Chief Coroners website). Furthermore the NICE QS 25 published in 2013 made a number of recommendations that are still valid. (the shortened version cut this down inappropriately in my view). To date only one of the NRAD recommendations (the NACAP) has been implemented and one has to ask whether the new guidelines will have any requirement for change in the management of asthma.	Thank you for your comment. We agree that there are problems in the delivery of asthma care and that there are important and useful recommendations for improvement from various sources which have not been implemented. However, the new Guideline will remain an advisory document.

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NHS England and Improvement - CYP Transformation Team - Asthma Oversight Group	General	General	We have seen during the SARS-COV-19 pandemic how our brilliant scientists have addressed and dealt with problems as they arose. So it would make far more sense, in my view, rather than relying solely on past material published for other purposes (including regulatory studies), to pose some key problems related to asthma care in the UK, for our scientists to address, perhaps using an adaptive type of design that so quickly and effectively identified how best to treat Covid-19 in the ICU.	Thank you for your suggestion. The Guideline will make research recommendations.
NHS England and Improvement - CYP Transformation Team - Asthma Oversight Group	General	General	Einstein said insanity is doing the same thing over and over again and expecting different results. The new guideline process is like just shuffling the deck chairs on the titanic rather than jumping ship and starting afresh. We have shown in many publications (starting with the one by the GPIAG soon after publication of the first UK asthma guideline - British Medical Journal. 1993;306:559-62) that guidelines are not adhered to, so we need to adopt a new approach regarding their presentation. It's time for different approaches and questions that might yield different/ improved outcomes rather than rehashing the same PICO questions over and over again.	Thank you for your comment. However, the developers would argue that adherence to the guideline can only be helped by ensuring that it is as up to date and correct as is feasible.

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NHS England and Improvement - CYP Transformation Team - Asthma Oversight Group	General	General	The key questions (particularly related to diagnosis, FeNO and Spirometry) have in the main been answered by the NHLBI update (2020), and the 2021 GINA update, so its difficult to justify the time until 2023 by reconsidering these questions and expecting different conclusions. This planned review will no doubt utilise previously published data and by 2023, that will all be out of date. Similarly the questions on drug treatment have also been recently dealt with and updated in these two publications. One large gap in the planned revision relates to the management of so called mild asthma which affects about half of the asthma population. In particular the overwhelming evidence in favour of ICS-formoterol in reducing severe attacks compared with using SABA currently advocated by NICE and SIGN/BTS. This is one area, in my view, that requires an urgent decision by this group in keeping with the NICE statement that recommendations may be made out with current regulatory status of medications. (40 countries worldwide have advocated this approach as a population safety measure to reduce moderate and severe attacks in people aged over 12.	Thank you for your comment. Guidance from other organisations may be included if they meet the criteria outlined in the methods manual https://www.nice.org.uk/process/pmg20/chapter/linking-to-other-guidance#guidance-from-other-developers
NHS England and Improvement -	General	General	The major problems with the list of key questions on diagnosis seem to be the failure to accept that there is no single diagnostic test for confirming asthma coupled with the	Thank you for your comment. The developers are aware that there is no single test which establishes the presence or absence of asthma. The evidence for each of the

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CYP Transformation Team - Asthma Oversight Group			fact that asthma is defined as a disease characterised by variable respiratory symptoms and variable airflow obstruction. So relying on a single test of lung function (spirometry or PEF) for diagnosis ids simply ludicrous. The NICE feasibility study showed that less than 30% of people diagnosed with asthma had abnormal spirometry. So to expect GPs to do serial spirometry in order to pick up variable airflow obstruction cannot work – so why persist with the question. Similarly, guidelines all over the world have concluded that FeNO alone cannot help in diagnosis – what's needed is a clinician with the skills to incorporate the history, response to treatment as well as the tests to make a diagnosis – so how will a string of statements in response to this long list of questions help a generalist to make a diagnosis?	potentially contributory tests will be updated, and the committee will make recommendations on the most useful combination of tests. The importance of symptoms in the diagnostic assessment will be made clear.
NHS England and Improvement - CYP Transformation Team - Asthma Oversight Group	General	General	The omission of severe and difficult to treat asthma from the scope is also a major flaw in my view. These patients t contribute significantly to the burden and cost of asthma in the UK – so why are they not being addressed. Similarly, the fact that asthma is a chronic condition requiring constant monitoring and adjustment of treatment when poorly controlled (ie risk factors like attacks as well as symptoms) is an indication that the key recommendation in NRAD ie	Thank you for your comment. Referral guidance will be included in this update. Severe and difficult asthma is extremely important but it is managed by specialist groups across the UK, not by generalists, and is therefore not included in the scope. However, BTS & SIGN will maintain their guidance on this topic and the NICE guideline will link to this.

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			referral to specialists after 2 attacks, plus a detailed post attack review should be done. The latter to assess and act if the attack is not resolved, as well as identification of modifiable risk factors which should be dealt with.	
NHS England and Improvement - CYP Transformation Team - Asthma Oversight Group	General	General	In my view, our aim should be to eradicate asthma attacks (and deaths) through a completely new national approach akin to that used in Finland would be a more appropriate method for solving our UK asthma situation. This should include a personalised asthma management cycle as described in GINA (the assess, adjust, review ongoing cycle which addresses issues related to diagnosis, identification and dealing with modifiable risk factors, patient preferences & goals, optimisation of management (not just drugs, but also education and inhaler technique) as well as appropriately timed review (not just an annual ' how's your asthma' check-up.	Thank-you for your comment. Although the terminology is not included, all of the elements of the personalised asthma management cycle are covered by current NICE and BTS/SIGN guidance and the intention is to retain these in this update.
NHS England and NHS Improvement	006	011	**General/page 6, General, Line 11 (proposed outline)** Our comment relates to the proposed outline for guidance. We would like to request that sufficient consideration is given to the environmental impact of inhalers, and specifically how to reduce carbon emissions from inhalers while improving patient outcomes. We note that the	Thank you for your comment. The importance of selecting the right inhaler device for each patient will be included in the guideline, and where devices are equally acceptable environmental factors will be taken into account. The developers recognise the need to consider these factors, but also the complexity of the environmental problem (considerations of disposal methods for different inhalers

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			intention is not to review the evidence and instead to editorially refresh and align the content already in the BTS/SIGN guidance. We would like to suggest there is a case to give greater emphasis and further expand on this, particularly as there have been some significant developments since the publication of the BTS/SIGN guidance in July 2019. We're sure you're already aware of these and only mention them to explain our rationale. The NHS has committed to reach net zero regarding the emissions it controls by 2040. Given 3% of NHS carbon emissions are estimated to come from inhalers, particularly metered-dose inhalers, this is now a key area focus for the NHS and the updated guidance would provide an opportunity to provide clear messaging on the importance of doing this whilst improving outcome for patients. July 2020, the BTS published a position statement with key recommendations on inhaler prescription BTS Environment and Lung Health Position Statement 2020.pdf (sustainablehealthcare.org.uk) and it would be useful to see these recommendations reflected in the new guideline.. In	for example) and therefore intend to recruit an expert on environmental issues to support the committee.

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			addition, a recent Asthma UK BLF study, presented at the European Respiratory Society congress, also suggests that most patients would be willing to try a more environmentally friendly inhaler and believe that the environmental impact of inhalers should be a consideration in treatment choices. This is reflected in NHS England & Improvement's approach on inhalers: improving patient outcomes (adherence, appropriate inhaler technique, patient choice, reduced overuse of short-acting beta agonist (SABA)) and reducing the carbon impact. We've deliberately taken these aims together as they are mutually reinforcing and because they reflect what patients want. The NHS' focus on emissions from inhalers is likely to drive changes in prescribing behaviours. In particular, indicators are due to commence in October as part of the Primary Care Network Investment and Impact Fund that will incentivise the prescribing of lower carbon inhalers (DPIs and SMIs for non-salbutamol inhalers, and lower average carbon emissions for salbutamol inhalers). These will be followed by indicators in the spring that will incentivise the prescribing of corticosteroid inhalers (ICS) and a reduction in the over-prescribing of short-acting beta agonist (SABA)	

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			inhalers. More details can be found on https://www.england.nhs.uk/wp-content/uploads/2021/08/B0828-iii-annex-b-investment-and-impact-fund-21-22-and-22-23.pdf. In support of these incentives, further, and more detailed, analysis is about to be published by PrescQIPP that will describe the life cycle carbon emissions associated with each different inhaler, based on available literature and information shared by manufacturers in a targeted questionnaire Current feedback from clinicians suggests that a revision of local formularies and guidelines will be required to reflect best practice in terms of prioritising lower carbon inhalers in a shared decision with patients, and the revised guidelines could help inform these revisions. Regarding disposal of inhalers, it is important to encourage all inhalers to be brought back to pharmacy along with all other unwanted medicines. This allows inhalers to be disposed of with other medicines waste, via high temperature incineration, which safely destroys the residual propellant gases, which are potent greenhouse gases.	

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			Encouraging return of used inhalers has been included in the latest Pharmacy Quality Scheme published in August (https://www.england.nhs.uk/wp-content/uploads/2021/09/Pharmacy-Quality-Scheme-guidance-September-2021-22-Final.pdf).	
NHS Sheffield CCG	General	General	I would like to see a greater emphasis on the green agenda within the document. It would be good for there to be something around pMDI SABA use highlighting its importance in the management of acute asthma symptoms and perhaps some reference to management of SABA over reliance	Thank you for your comment. The committee will co-opt an expert to discuss the environmental impact of the recommendations. The recommendations in the BTS/SIGN guideline in section 'the environmental impact of metered-dose inhalers' will be editorially refreshed and aligned. The guideline will also cross refer to the NICE decision aid on inhalers which considers the environmental impact https://www.nice.org.uk/guidance/ng80/resources/inhalers-for-asthma-patient-decision-aid-pdf-6727144573.
NHS Sheffield CCG	General	General	Improving compliance in asthma – could the guidance look at the use of once daily treatments and MART regimes to help improve compliance to therapies and asthma management - review of the evidence behind this etc	Thank you for your comment. Single Maintenance and Reliever Therapy [SMART] or Maintenance and Reliever Therapy [MART]) therapies are included in the scope of this guideline (see draft question 3.2).
NHS Sheffield CCG	005	011	In this table it refers to the NICE guideline age ranges of under 5 5-16 and 17+. I would like to see consideration of revising these age ranges to align with the current ranges used by BTS/SIGN as they more accurately match the	Thank you for your comment. The age categories will be defined by the guideline committee during the development of the guideline.

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			licencing characteristics of inhalers. Having a 5-16 age range causes complexity for clinicians as many inhalers are licenced from 12 years of age and therefore the same treatment pathways cannot be used throughout the group. Under 5, 5-12 and 12+ and adults fits better.	
NHS Sheffield CCG	011	015	Good to see that there is going to be consideration of PRN ICS/LABA for treatment naïve patients. Strongly support this.	Thank you for your comment. Sequencing and combination of medicines is included in the scope of this guideline.
NHS Sheffield CCG	011	021	SMART = single maintenance and reliever therapy? I have never seen SMART referred to in this way. In clinical practice SMART was always Symbicort maintenance and reliever therapy as it was they first MART therapy available. I think this would be better simply referred to as MART	Thank you for your comment. The terminology has been used previously.
Novartis Pharmaceuticals UK Limited	General	General	The current scope excludes documents linked to the published NICE guideline NG80 such as the "Inhalers for asthma (patient decision aid)". This document should be reviewed and updated once evidence for pharmacological management of asthma is reviewed to take into consideration new inhaler devices containing fixed dose triple therapy combinations and digital tools available for patients to use with their asthma inhalers such as electronic sensors	Thank you for your comment. We have added the decision aid to the section on related NICE guidance. Smart inhalers (a new review question has been added) will be reviewed in this guideline. Fixed dose triple therapy combinations per se will not be reviewed, but their pharmacological components will be included.

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Novartis Pharmaceuticals UK Limited	General	General	Please consider adding a section on referral guidance including when to refer patients and minimum standards for referral centres.	Thank you for your comment. The committee will consider referral criteria but setting standards for referral centres is beyond the remit of a guideline.
Novartis Pharmaceuticals UK Limited	General	General	Inhaler technique is commonly poor amongst patients. Inhalers constitute the mainstay of treatment in the majority of patients and a large number of inhaler devices are available. Please consider including a section on inhaler technique including minimum standards for training healthcare providers and regularity of assessments for patients using inhalers.	Thank you for your comment. Both BTS/SIGN and NICE guidelines currently recommend checking inhaler technique when changing or instigating treatment and at regular reviews, and the importance of doing so will be included in this update. However, it is outside the remit of a guideline to set training standards.
Novartis Pharmaceuticals UK Limited	General	Question 1	Fixed dose triple therapy combinations for asthma are now available in the UK. They provide cost savings compared to using separate inhalers (ICS/LABA + LAMA)	Thank you for your comment. The effect of combining ICS + LABA + LAMA is included in the scope of this guideline (review question 3.2) but specific formulations will not be compared. Prescribers can choose between available options based on multiple factors including inhaler technique and patient preference as well as cost.
Novartis Pharmaceuticals UK Limited	General	Question 1	Enerzair Breezhaler (indacaterol acetate/glycopyrronium bromide/mometasone furoate) has been recognised by European medicines evaluation agency as a medicine that brings outstanding contribution to public health due to being the first asthma triple combination therapy that includes an optional electronic sensor to collect data on the use of the	Thank you for your comment.

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Stakeholder	Page no.	Line no.	Comments Please insert each new comment in a new row	Developer's response Please respond to each comment
			inhaler by the patient human-medicines-highlights-2020_en.pdf (europa.eu)	
Novartis Pharmaceuticals UK Limited	006	Adherence	There are multiple techniques available to address adherence including review of electronic prescribing records and smart inhalers. Evolving evidence suggests smart inhalers and digital sensors may contribute to improvement of adherence with asthma inhalers. Therefore, it is suggested to undertake an evidence review to provide guidance around the potential benefits of smart inhalers and digital sensors to asthma patients and identify which asthma patients may benefit more from such interventions. (e.g. Normansell *et al*. Cochrane Library 2017;20:doi:10.1002/14651858; Morton RW et al Thorax 2017;72:347-354)	Thank you for your comment. We had added a draft review question on the clinical and cost effectiveness of smart inhalers (4.1) to the scope.
Novartis Pharmaceuticals UK Limited	006	Inhaler devices including their impact on the environment	The current draft scope excludes reviewing the evidence regarding the impact of inhaler devices on the environment, however there is evolving evidence to highlight the difference in the carbon footprint between inhaler devices and it is important to provide guidance to healthcare professionals on how this should be integrated in clinical decision making. (e.g. Janson C et al Thorax. 2020;75(1):82-84. doi:10.1136/thoraxjnl-2019-213744 Fulford, B. et al, Sustainability 2021, 13, 6657. https://doi.org/10.3390/su13126657)	Thank you for your comment. Where devices are equally acceptable environmental factors will be taken into account, and it is intended to recruit an expert on environmental issues to support the committee when considering these issues

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Novartis Pharmaceuticals UK Limited	006	Management of acute asthma	Inclusion of management of acute asthma may encourage coordination / continuation of treatment across scheduled and unscheduled visits.	Thank you for your comment. Guidance on the management of Acute Asthma will be maintained by BTS/SIGN and signposted within the NICE guideline.
Novartis Pharmaceuticals UK Limited	007	017	Inclusion of the management of difficult asthma would be relevant even for less severe asthma patients and inclusion is requested in this guideline. Early identification and management of differential diagnoses and comorbidities would facilitate effective treatment, even from the onset of symptoms.	Thank you for your comment. Severe and difficult asthma is extremely important but it is managed by specialist groups across the UK, not by generalists, and is therefore not included in the scope. However, BTS & SIGN will maintain their guidance on this topic and the NICE guideline will signpost to this.
Novartis Pharmaceuticals UK Limited	007	019	Inclusion of phenotyping would be relevant even for less severe asthma patients and inclusion is requested in this guideline. Early phenotyping will allow measures to be implemented from the outset (e.g. trigger and allergen avoidance).	Thank-you for your comment. The current NICE guideline recommends assessment of asthma triggers at first presentation and during monitoring. The developers are not aware of evidence that more comprehensive routine phenotyping is useful in non-severe asthma. The role of FeNO measurement is included in the Scope.
Novartis Pharmaceuticals UK Limited	010	010	The diagnostic test accuracy and cost effectiveness of skin prick testing in children will be considered. It is requested that the accuracy and cost-effectiveness of these measures in adults also be considered. Allergic asthma can occur in adults. (Shaw et al. European Respiratory Journal Nov 2015, 46 (5) 1308-1321 demonstrated the presence of	Thank you for your comment. It is acknowledged that allergic asthma occurs in adults as well as children, but routine skin prick testing (as opposed to targeted testing directed by the history) does not alter the management of asthma. The situation is different in children in whom other

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			atopy in 70-90% of patients with asthma vs 46% of healthy controls).	tests for asthma may not be feasible and skin prick results could help toward a diagnosis.
Novartis Pharmaceuticals UK Limited	010	013	The diagnostic test accuracy and cost effectiveness of total and specific IgE testing in children will be considered. It is requested that the accuracy and cost-effectiveness of these measures in adults also be considered. Allergic asthma can occur in adults (Shaw et al. European Respiratory Journal Nov 2015, 46 (5) 1308-1321 demonstrated the presence of atopy in 70-90% of patients with asthma vs 46% of healthy controls).	Thank you for your comment. It is acknowledged that allergic asthma occurs in adults as well as children, but routine specific IgE testing (as opposed to targeted testing directed by the history) does not alter the management of asthma. The situation is different in children in whom other tests for asthma may not be feasible and specific IgE could help toward a diagnosis.
Primary Care Respiratory Society	005		Diagnosis section should be streamlined and discrepancies addressed: o NICE 2019 asks for spirometry and FeNO as **essential** whereas BTS guidance is more practical as based on structured assessment ▪ Negative Spirometry and FeNO in an asymptomatic patient with BTS-high probability suspected asthmatic may incorrectly diagnose as a non-asthmatic if just NICE guidance is followed in primary care and that will lead to under-diagnosis of asthma resulting into increase in potential risk of ED	Thank you for your comment. The scope of the guideline includes a new evidence review on spirometry, FeNO and eosinophils, and recommendations will be made based on this.

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			attendances and hospitalisation during their flare ups of such undiagnosed patients? Usefulness of peripheral blood eosinophils must be recommended while making structured assessment	
Primary Care Respiratory Society	005		The key questions (particularly related to diagnosis, FeNO and Spirometry) have in the main been answered by the NHLBI update (2020), and the 2021 GINA update, so it's difficult to justify the time until 2023 by reconsidering these questions and expecting different conclusions.	Thank you for your comment. This guideline will be produced in accordance with NICE methods https://www.nice.org.uk/process/pmg20/chapter/introduction to ensure that the recommendations improve patient outcomes in England and Scotland.
Primary Care Respiratory Society	005		Value of diagnostic pathways should be evaluated not just the utility of individual diagnostic tests	Thank you for your comment. The diagnostic pathway will be updated as part of this scope. A draft review question has been added on the diagnostic accuracy of combination of tests (1.10)
Primary Care Respiratory Society	005		The major problems with the list of key questions on diagnosis seem to be the failure to accept that there is no single diagnostic test for confirming asthma coupled with the fact that asthma is defined as a disease characterised by variable respiratory symptoms and variable airflow obstruction.	Thank you for your comment. The developers are aware that no single test correctly identifies or excludes asthma. The evidence for each of the potentially contributory tests will be updated, and the committee will make recommendations on the most useful combination of tests. A draft review question has been added on the diagnostic accuracy of combination of tests (1.10).

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Primary Care Respiratory Society	005		The NICE feasibility study showed that less than 30% of people diagnosed with asthma had abnormal spirometry. So to expect GPs to do serial spirometry in order to pick up variable airflow obstruction cannot work – so why persist with the question.	Thank you for your comment. Neither the scope, nor the existing NICE and BTS/SIGN guidelines, advocate serial spirometry. This question relates to a single measure of spirometry.
Primary Care Respiratory Society	005		Lessons from COVID-19: Usefulness of PEFR measurements for diagnosis should be emphasised	Thank you for your comment. The diagnostic accuracy of peak flow is included in the scope (draft review question 1.3).
Primary Care Respiratory Society	005		Discrepancies between pharmacological recommendations by NICE/BTS/SIGN must be corrected to avoid confusion	Thank you for your comment. The pharmacological management is included in the scope of this joint guideline.
Primary Care Respiratory Society	005		The questions on drug treatment have also been recently dealt with and updated in the NHLBI update (2020), and the 2021 GINA update	Thank you for your comment.
Primary Care Respiratory Society	005		One large gap in the planned revision relates to the management of so called mild asthma which affects about half of the asthma population. In particular the overwhelming evidence in favour of ICS-formoterol in reducing severe attacks compared with using SABA currently advocated by NICE and SIGN/BTS. This is one area that requires an urgent decision by this group in keeping with the NICE statement that recommendations may be made without current regulatory status of	Thank you for your comment. Mild asthma is included in the scope of this guideline (for example see draft review question 3.1).

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			medications. (40 countries worldwide have advocated this approach as a population safety measure to reduce moderate and severe attacks in people aged over 12).	
Primary Care Respiratory Society	005		There is a need to evaluate the data behind the GINA guidance as soon as possible and it would seem that this would be an ideal time to undertake such a review. Indeed, members reported that pragmatically, they have already begun the use Symbicort PRN for mild asthma as this makes sense in so many ways – not just in improving outcomes, but also in reducing SABA over-reliance and reducing prescribing of high carbon footprint inhalers.	Thank you for your comment. The use of ICS/LABA combinations in mild asthma is included in the scope.
Primary Care Respiratory Society	005		An update to the ICS potencies chart would be useful eg uncertainties/discrepancies around fluticasone furoate and now there's new combination treatment with mometasone furoate which makes it hard to know whether it's low, medium or high ICS potency in a breezhaler device	Thank you for your comment. The NICE ICS potency chart will be updated.
Primary Care Respiratory Society	005		Cost-effectiveness should not be the main consideration in developing these guidelines	Thank you for your comment. These guidelines consider both clinical and cost effectiveness in accordance with the processes outlined in the methods manual (https://www.nice.org.uk/process/pmg20/chapter/introduction).

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Primary Care Respiratory Society	005		Impact of comorbid conditions on asthma control should be considered. Awareness and management of common comorbid conditions that may act as asthma triggers such as allergic rhinitis? Appropriate diagnosis and management of such conditions has the potential to improve asthma control without the need to increase ICS use	Thank you for your comment. It is expected that comorbid conditions should be managed in accordance with the relevant NICE guidance.
Primary Care Respiratory Society	005		There is no mention of strategies to maintain good asthma control. Will this be covered in the 'self-management' section?	Thank you for your comment. Maintaining good control will be covered in self-management, in monitoring, and in recommendations on asthma review.
Primary Care Respiratory Society	005		The key problems related to asthma care and the comparatively bad UK asthma outcomes worldwide have not been addressed by this scoping document. These relate to quality and consistency of care within primary and secondary sectors as well as the interface between these and the tertiary care sector. The issues have been detailed in a number of UK reports of note the NRAD (2014), the APPG report (2020), the HSIB report (2021), the NACAP results as well as in the HM Coroners Regulation 28 reports on Ella, Kissi-Debra, Tamara Mills, Michael Uriely, Sophie Holman and countless others (published on HM Chief Coroners website). Furthermore the NICE QS 25 published in 2013 made a number of recommendations that are still valid. To date only one of the NRAD recommendations (the	Thank you for your comment. We agree that there are problems in the delivery of asthma care and that there are important and useful recommendations for improvement from various sources which have not been implemented.

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			NACAP) has been implemented and one has to ask whether the new guidelines will have any requirement for change in the management of asthma.	
Primary Care Respiratory Society	006		Adherence: this is critical to achieve asthma control. Merging this section with 'self-management' risks shifting the focus onto patients to maintain asthma control and away from HCPs identifying and providing support when there is evidence of poor control	Thank you for your comment. The developers believe that the focus of adherence should be on the patient whilst acknowledging that healthcare professionals should provide support.
Primary Care Respiratory Society	006		Usefulness and guidance on usage of FeNO in asthma monitoring in primary care must be recorded. Should be clear that FeNO is a tool to guide management interventions not just to monitor patients.	Thank you for your comment. This role of FeNO measurement will be included in the update.
Primary Care Respiratory Society	007		Why is biologic treatment excluded? Once again this risks multiple asthma guidelines	Thank you for your comment. Biologic therapies are already covered by NICE Technology Appraisals. Links to these will be included in the Guideline.
Primary Care Respiratory Society	007		Why is there no mention of non-pharmacological interventions such as breathing techniques? Will these be included in self-management?	Thank you for your comment. The recommendations on non-pharmacological management which includes breathing techniques in the BTS/SIGN guideline will be maintained in separate guidance.
Primary Care Respiratory Society	007		Why is there no interface with known environmental triggers such as smoking, poor housing conditions (damp, mold), or	Thank you for your comment. The recommendations on non-pharmacological management which includes

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			deprivation. These are critical factors for prevention and control of asthma	environment triggers in the BTS/SIGN guideline will be maintained in separate guidance.
Primary Care Respiratory Society	007	005	**Difficult asthma:** How is this going to be defined? How will difficult to manage (patient factors) vs difficult to treat (eg treatment/device factors) vs severe asthma (pathological factors) be distinguished. The omission of severe and difficult to treat asthma from the scope remains a concern and may limit the effectiveness of these guidelines to drive down the burden and mortality associated with asthma in the UK. The fact that asthma is a chronic condition requiring constant monitoring and adjustment of treatment when poorly controlled (ie risk factors like attacks as well as symptoms) is an indication that the key recommendation in NRAD ie referral to specialists after 2 attacks, plus a detailed post attack review should be done. The latter to assess and act if the attack is not resolved, as well as identification of modifiable risk factors which should be dealt with.	Thank you for your comment. Severe and difficult asthma is extremely important but it is managed by specialist groups across the UK, not by generalists, and is therefore not included in the scope. However, BTS & SIGN will maintain their guidance on this topic and will address definitions and distinctions as appropriate. The NICE guideline will signpost to BTS/SIGN.
Primary Care Respiratory Society	007	005	Given that the aim of asthma management is to eradicate asthma attacks and deaths any guideline should reflect the real life situation and requirements of patients with the disease. This should include a personalised asthma	Thank-you for your comment. Although the terminology is not included, all of the elements of the personalised asthma management cycle are covered by current NICE

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			management cycle as described in GINA (the assess, adjust, review ongoing cycle which addresses issues related to diagnosis, identification and dealing with modifiable risk factors, patient preferences & goals, optimisation of management (not just drugs, but also education and inhaler technique) as well as appropriately timed review (not just an annual "how's your asthma" check-up). This requires a joined up approach to service provision with a seamless interface between primary and secondary care as opposed to a silo approach of placing asthma patients in defined categories of severity and control when in reality they may often cycle between severity levels and levels of control.	and BTS/SIGN guidance and the intention is to retain these in this update.
Primary Care Respiratory Society	7	12-19	Concerns were raised about the exclusion of guidance on acute asthma management from this guideline. Specifically, there were concerns that exclusion of acute management would result once again in multiple guideline documents for HCPs to consult. A consolidated, single guideline encompassing all aspects of asthma management would be of more practical use for HCPs working in primary care and more reflective of the real world situation of patients with asthma.	Thank you for your comment. Guidance on the management of Acute Asthma will be maintained by BTS/SIGN and signposted within the NICE guideline.
Royal College of Nursing	General	General	We are supportive of the update and approach to address the current conflicting guidance.	Thank you for your comment.

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Royal College of Nursing	General	General	The plan to develop a new asthma clinical pathway (joint guideline produced by BTS, SIGN and NICE) on diagnosing and managing asthma throughout a person's lifetime appears a sensible approach.	Thank you for your comment.
Royal College of Nursing	General	General	It will be important to have nursing representation across the entire pathway as part of the guideline group.	Thank you for your comment. We have advertised for an adult and paediatric specialist respiratory nurse and practice nurse/community nurse/ nurse practitioner to be full members of the guideline committee.
Royal College of Paediatrics and Child Health	General	General	The incidence of non-communicable diseases such as Bronchial Asthma is a growing concern and evidence suggests that this disproportionate burden among certain ethnic groups is the result of complex interactions between genetic risk and lifestyle factors.	Thank you for your comment. We agree that there is a complex interplay of factors that lead to increased risk of problems in different groups. There is not yet a robust understanding of genetic variations that impact on asthma, nor indeed a detailed understanding of the other mechanisms for ethnic and racial differences in outcome. At this time, therefore, we would be unable to formulate different management approaches to asthma in different groups. However, the NHSE toolkit for CYP asthma does have a focus on local approaches to care, and this should help identify strategies for communities that are tailored around their needs.
Royal College of Paediatrics	General	General	Recent within country comparisons have revealed that despite originating from areas of the world with a low risk of	Thank you for your comment. The developers are aware of this evidence although, regrettably, not aware of hard

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and Child Health			developing Asthma, South Asian and Afro Caribbean children in the UK are significantly more likely to be admitted to hospitals for Asthma related problems than White children.	evidence on how to address the issue. There is insufficient evidence to develop ethnicity-specific guidelines for The evidence on outcomes is not as strong for Afro-Caribbean populations, and it may be a different problem since it appears that asthma is more common in those of Afro-Caribbean origin and hence the increased consultations and admissions may be proportional. We have edited the Equalities Impact Assessment to include Afro Caribbean children. NICE has approached the NIHR to ask if research in this area can be promoted and prioritised. The NICE surveillance team will monitor this issue and consider updating the guideline when evidence becomes available..
Royal College of Paediatrics and Child Health	General	General	In addition to early and appropriate interventions, further efforts need to be made by healthcare professionals to raise awareness of symptoms and effectively communicate how, when and where to seek help for children, and to ensure consistency of care. Information should be conveyed in a language known to the parents.	Thank you for your comment. This guideline will cross refer to the NICE guideline on patient experience which includes recommendation on communication and information provision https://www.nice.org.uk/guidance/cg138. The NHSE Toolkit for CYP asthma is around delivery of care, including when and where this should be sought. The "Early and Accurate Diagnosis" workstream has particular focus on improving public understanding of asthma.
Royal College of Paediatrics	General	General	The reviewers were happy with the suggestion to develop and update a unified asthma guideline for the UK.	Thank you for your comment

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and Child Health				
Royal College of Physicians	General	General	The RCP is grateful for the opportunity to respond to the above consultation. We would like to endorse the response submitted by the British Thoracic Society (BTS).	Thank you for your comment.
Royal Hospital for Children and Young People, Edinburgh	004	019	It is important that the age cut offs are well defined. For example will this guideline include children down to 2 years old?	Thank you for your comment. The age cut-offs will be defined further by the guideline committee during development. Children down to 2 years old are included in the scope of the guideline.
Royal Hospital for Children and Young People, Edinburgh	006		**1st 3 rows of table** Not clear what an asthma clinical pathway means. Is this a separate document? Would be disappointing to lose the holistic nature of the previous formats. Asthma in adolescents is a really important area. Deaths in the UK are higher in this age group than in other countries. Surely we should be reviewing this.	Thank you for your comment. The description of the pathway has been edited. As part of the collaboration between BTS/NICE and SIGN a broader set of guidance and materials will be developed, drawing on those that have been produced by these organisation, on diagnosing and managing asthma throughout an individual's lifetime – a new 'asthma pathway'. This will be developed by the steering group. The diagnosis and management of asthma in adolescents is included in the scope of this guideline.

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Royal Hospital for Children and Young People, Edinburgh	006		**rows 6 and 8** Why not review of adherence. There has been huge progress made in adherence in asthma, esp. in children and young people. Guideance is needed	Thank you for your comment. The developers are aware of no new evidence that would impact on the recommendations on adherence with the exception of smart inhalers (see new draft review question 4.1)
Royal Hospital for Children and Young People, Edinburgh	007	008	What is the asthma clinical pathway. Needs description. Surely should be agreed as part of the scope.	Thank you for your comment. The description of the pathway has been edited. As part of the collaboration between BTS/NICE and SIGN a broader set of guidance and materials will be developed, drawing on those that have been produced by these organisation, on diagnosing and managing asthma throughout an individual's lifetime – a new 'asthma pathway'. This will be developed by the steering group.

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Royal Hospital for Children and Young People, Edinburgh	009	025	It is worrying that symptoms and signs are being excluded from the review. This assumes that tests are more useful in all age groups (children esp. cannot reliably be diagnosed using tests alone). Often the only information is symptoms and signs for younger children. By excluding this from the evidence review, it reveals a bias that sympoms and signs are not useful. This is not agreed across the board.	Thank you for your comment. Symptoms and signs are not included in the evidence review, but this does not mean that they are excluded from the guideline. The developers are well aware of the importance of the clinical history, and this will be made clear in the guidance. However, both BTS/SIGN and NICE have previously reviewed the relevant evidence and the developers do not believe that there is substantial new data to justify a further review.
Royal Hospital for Children and Young People, Edinburgh	010	General	I would need assurance that age will be taken into account. If you include only the tests that younger children can perform there is not much left, hence why symptoms and signs evidence needs to be reviewed.	Thank-you for your comment. The influence of age on ability to perform tests will be taken into account.
Royal Hospital for Children and Young People, Edinburgh	011	007	There is a lot of progress in telemedicine and adherence monitoring since the most recent guidelines. Surely this should be included.	Thank you for your comment. A question on the use of smart inhalers in improving adherence has been added to the scope. Although there is a lot of interest in telemedicine the developers are not aware of any substantial research which would change current recommendations

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Royal Hospital for Children and Young People, Edinburgh	011	012	You haven't included regular ICS/LABA. Most patients are managed on this regime. Why is it not included?	Thank you for your comment. Regular ICS/LABA is included in the scope of this guideline (draft review question 3.1).
Royal Hospital for Children and Young People, Edinburgh	011	020	Again, it is slightly confusing to say ICS plus LABA with SABA PRN. ICS plus LABA is a regular treatment.	Thank you for your comment. At this point in the treatment pathway, regular ICS plus LABA is an option which will be considered in the review
Royal Hospital for Children and Young People, Edinburgh	011	030	Diagnostic tests can't always be performed by young/immature children with asthma. Symptom pattern and signs need to be included	Thank you for your comment. The importance of symptoms and signs will be included in the guideline
Teva UK Limited	General	General	We want to flag and ensure in light of the approximate 3 year development timeline that it ensures timely inclusion of new licenses, new products and research that will be launched over the 2 years before expected publication so it is as up-to date as possible.	Thank you for your comment. The literature searches are re-run towards the end of the development of the guideline to ensure that any evidence that meets the review protocol criteria published is included.
Teva UK Limited	006	011	Both sections entitled 'Adherence' (in the existing NICE guidelines) and 'Inhaler devices including their impact on the environment' in BTS/SIGN respectively are only planned to editorially refresh & align. We would query whether there	Thank you for your comment. The developers are aware of no new evidence that would impact on the

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			is a need to review the evidence with regards these topics considering the constant publication of new data particularly regarding the environmental impact of inhalers in recent months and the continuous development of novel digital technologies that aid adherence and will likely continue to advance during the scoping process to ensure the guidelines are as relevant as possible at time of publishing once again.	recommendations on adherence with the exception of smart inhalers (see new draft review question 4.1). Where devices are equally acceptable environmental factors will be taken into account, and it is intended to recruit an expert on environmental issues to support the committee when considering these issues.
The AHSN Network	General	General	The AHSN Network welcomes this scope and supports the content.	Thank you for your comment.
The AHSN Network	General	General	The NHS England Accelerated Access Collaborative is currently 6 months into a 24 month FeNO change programme, with delivery being led by the AHSN Network. There is an opportunity for the real world learning from this programme to feed into future NICE/SIGN/BTS guidance.	Thank you for your comment.
The AHSN Network	General	General	It is suggested that the updated guidance links to the future operational set up of respiratory testing – e.g. Community Diagnostic Hubs, and primary care/PCN based respiratory hubs.	Thank you for your suggestion.
The AHSN Network	General	General	**FeNO being used in diagnosis or monitoring** There is one part missing which is the mention of FeNO being used in diagnosis or monitoring. One nuance that needs considering is that FeNO is a modality for diagnosing	Thank you for your comment. The evidence on use of FeNO will be reviewed**, but t**he strategy you advocate for use of FeNO in monitoring is exactly that recommended in current NICE guidance. In relation to use of FeNO in

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			undiagnosed eosinophilic inflammation – not just in the diagnosis of asthma but also in diagnosis of persistent symptoms in people already diagnosed with asthma. Current clinical practice is to optimise treatment and usually to increase treatment (usually to a higher dose inhaled corticosteroid inhaler) which may or may not be appropriate and carries significant cost to the NHS and an increased side effect burden for patients. FeNO can be used to assess people with persistent chest symptoms to see whether optimisation of the treatment of eosinophilic inflammation. FeNO (probably) has no role in the routine monitoring of patients with well-controlled asthma but has a key role in the assessment of people with persistent symptoms. It would be inappropriate to generalise and say that there is no role in monitoring. It would be more appropriate to consider the role of FeNO is monitoring/reassessing patients with persistent chest symptoms as part of a detailed clinical assessment.	diagnosis, NICE are currently considering commissioning a guideline on undiagnosed breathlessness.
The AHSN Network	General	General	**Gaps in knowledge**	Thank you for your suggestion. We have added a review question on the diagnostic accuracy of combinations of tests.

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			It would be good to highlight gaps in knowledge (as these often lead to targeted research opportunities) around FeNO. One gap that we identified was the sensitivity and specificity of combinations of tests to diagnose asthma. We should highlight any other gaps raised as part of the literature search.	
The AHSN Network	006	011	Table **Risk stratification - Review evidence: update existing recommendations as needed** The AHSN network welcomes the review of guidance around risk stratification of asthma patients. Given one of the areas of focus of the AHSN Network activity currently is around early identification of uncontrolled asthma patients we recognise that the use of explicit risk stratification rules alongside appropriate education, support and guidance will aid decision-making around asthma care and see more patients optimised with their medicines[1,2,3]. Through the ongoing AAC/AHSN Network Asthma Biologics programme a number of real-world evaluations will be taking place on some established risk stratification criteria in primary care[4]. These evaluations would likely read out in Sept 2022 but could, where appropriate be shaped with	Thank you for your comment and your suggestion. Work in progress cannot be included in the Scope but, if your evaluations are completed before the end of guideline development and are relevant to our question, results should be captured by our searches.

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			input from NICE on the outcomes and measures likely to be valuable in assessment 1. Abrahamsen R, et al. (2020) PLOS ONE 15(5): e0232621 2020 https://doi.org/10.1371/journal.pone.0232621 2. UCL Partners, Proactive Care Frameworks - Asthma, 2021 https://s31836.pcdn.co/wp-content/uploads/Asthma-FINAL.pdf 3. Asthma UK, Connected Asthma, 2016 https://tinyurl.com/yrkdtvpc 4. AstraZeneca/ AAC Severe Asthma Risk Stratification Tool https://suspected-severe-asthma.co.uk/ (accessed Sept 2021)	
The AHSN Network	006	011	Table **Adherence: No evidence review: editorially refresh and align recommendations. This will be merged with the section on self-management** While the extent of suboptimal adherence in asthma and its significant impact on both morbidity and mortality is acknowledged, few interventions have been reported to have impact on improving it in practice. We know clinicians	Thank you for your comment. The developers are aware of no new evidence that would impact on the recommendations on adherence with the exception of smart inhalers (see new draft review question 4.1)

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			frequently underestimate the extent of non-adherence in their patients, and the size of the impact on treatment[1]. Clinicians often do not have the skills to navigate conversations around adherence with their patients and where they do enquire about adherence in consultations, often they do so in ways which make patients unwilling to disclose it. Given the trends towards lapses into non-adherent behaviours, adherence should be considered as a critical and chronic concern, requiring extended monitoring and on-going support. The AHSN network appreciates there is a paucity of evidence supporting the utility of large-scale interventions to improve long-term adherence. However, understanding the reasoning behind non-adherence may help clinicians implement interventions to better support it for an individual. Whilst we appreciate the decision of NICE not to conduct an evidence review, given the complexity of this area, the importance of this topic to asthma care warrants more than an editorial refresh. 1. Gráinne d'Ancona et al, Breathe 2021, 17 (2) 210022; DOI: 10.1183/20734735.0022-2021	

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The AHSN Network	007	017	***Difficult and Severe asthma will not be included in this update.*** Severe Asthma accounts for only a small proportion of Asthma patients (~5%). However severe asthma has a far more significant impact on patients than the mild/ moderate disease. We now understand that severe asthma has a disproportionate burden in terms of the utilisation of health care services, impairment of quality of life and immeasurable human suffering due to recurrent exacerbations. The direct costs associated with these patients cover around 60% of total costs of treating asthma patients.[2,3] Currently it is estimated that as many as 72% of patients on the highest asthma therapy level (GINA step 4 or 5) and with 2 or more exacerbations per year have not been reviewed or referred to secondary care in the last year[4]. Furthermore, access to the novel biologic therapies which could have life-changing implications for severe asthma patients are currently access by less than 20% of those eligible[5]. Often patient not identified or able to access severe asthma care will be maintained on oral	Thank you for your comment. Severe and difficult asthma is extremely important but it is managed by specialist groups across the UK, not by generalists, and is therefore not included in the scope. However, BTS & SIGN will maintain their guidance on this topic and the NICE guideline will signpost to this. The guideline will also include referral criteria; this has been added to the scope.

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			corticosteroids which also has detrimental effects to patients health over time[6]. Through the Accelerated Access Collaborative Asthma Biologics programme, the AHSN Network has led engagement nationally with a huge range of stakeholders involved in asthma care. Asthma care and severe asthma has been elevated to being a priority for many regions with AHSN-led improvement activity taking place nation-wide. A number of pieces of work have highlighted a clear need for fully evidenced guidelines with clear referral criteria as a signal top all parts of the system about the appropriate and expected standards of care for these patients. • A NICE-owned scoping exercise was completed which identified several key themes to improve care for severe asthma patients. These included clarifying and improving elements of the care pathway in primary, secondary and tertiary care[7]. • A recent national benchmarking exercise conducted by the AHSN network highlighted significant variation in the quality of and access to care for Severe Asthma patients[8].	

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			• A recent report by Asthma UK summarises the evidence on the risks of oral steroids, explaining the rationale and criteria for referral[9]. • A national audit of waiting times for severe asthma care has been conducted which looks at key stages of referral, initiation consultation, decisions to treat with biologics and initiation treatments. Publication expected in October. In the absence of formal NICE guidance around severe asthma care, the Accelerated Access Collaborative team have initiated a workstream to develop a consensus pathway with all key organisations likely to involved in severe asthma care including NHSE, NICE, Providers, BTS, PCRS, ARNS, AHSN Network, Asthma UK, Industry and most importantly patients. Whilst the developmental NICE Quality Standard, and the rapid guideline for the treatment of severe asthma was welcomed by the AHSN network in providing a definition of severe asthma, more is needed in this space. The	

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			upcoming review of asthma guidelines and pathways between NICE, BTS and SIGN is an ideal opportunity to address this. 1. Fernandes AG et al, *J Bras Pneumol*. 2014; 40(4): 364-372 2. Sadatsafavi M et al. *Can Respir J* 2010; 17: 74-80. 3. Sullivan SD, Rasouliyan L, Russo PA, et al. *Allergy* 2007;62:126–33. 4. Ryan et al, *J Allergy Clin Immunol* Pract 2021 5. BlueTeq Data accessed as part of AAC Asthma Biologics programme 6. Price, D. B., Trudo, F., Voorham, J., et al. *Journal of Asthma and Allergy*. 2018; 11:193-204. 7. Hookway et al., AAC Report - Possible Solutions to Adoption Barriers (Report), Feb 2021 8. Oxford AHSN, AHSN Network Benchmarking Report (Report), Sept 2021 9. Asthma UK, Do No Harm (Report) Feb 2021	
The AHSN Network	012	010	NICE DG12 (Measuring fractional exhaled nitric oxide concentration in asthma: NIOX MINO, NIOX VERO and NObreath) is from 2014. We feel that this guidance should also be updated along with the update to NG80 to reflect	Thank you for your comment. The evidence on use of FeNO will be reviewed

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			updates to the available technologies and associated evidence – I.e. the Circassia NIOX MINO device is no longer sold by the supplier and other testing devices are now available such as the Vivatmo by Bosch.	
The Breastfeeding Network	General	General	We feel that it would be beneficial to include within the scope, and subsequent final guideline, the treatment of asthma in breastfeeding mothers. This could perhaps be included within, or follow on from, the section on Intrapartum care/Asthma in pregnancy. The BTS SIGN guideline for the management of asthma states: "The medicines used to treat asthma, including steroid tablets, have been shown in early studies to be safe to use in breastfeeding mothers. There is less experience with newer agents. Less than 1% of the maternal dose of theophylline is excreted into breast milk. Prednisolone is secreted in breast milk, but milk concentrations of prednisolone are only 5–25% of those in serum. The proportion of an oral or intravenous dose of prednisolone recovered in breast milk is less than 0.1%. For maternal doses of at least 20 mg once or twice daily the nursing infant is exposed to minimal amounts of steroid with no clinically significant risk.	Thank you for your comment. This guideline will editorially refresh and align the recommendations from the NICE and BTS/SIGN guideline on pregnancy and this includes breastfeeding.

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			Encourage women with asthma to breastfeed. Use asthma medications as normal during lactation, in line with manufacturers' recommendations." https://www.brit-thoracic.org.uk/quality-improvement/guidelines/asthma/ Despite asthma treatments being considered safe for breastfeeding mothers, the Breastfeeding Network Drugs in Breastmilk information service still receives enquiries from breastfeeding mothers concerned about the safety of their asthma medications for their breastfed children. Including this information in the guideline could help ensure that all healthcare professionals and mothers are aware that asthma treatments are compatible with breastfeeding. Breastfeeding is widely recognised to be beneficial in infant health. It is protective lower respiratory tract infections in infants, and may be protective against the development of asthma (Oddy, 2017 ANM457920.indd (karger.com)). It is therefore important that all mothers are supported and encouraged to breastfeed whilst using their asthma medications as required.	
University Hospitals	General	General	Diagnosis: Diagnostic criteria differences between NICE vs BTS require aligning (role of FeNO in asthma	Thank you for your comment. The diagnostic accuracy of FeNO is included in the scope of this guideline (draft

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Birmingham NHS Foundation Trust			diagnosis needs consideration for FeNO low asthma phenotypes "e.g. in smokers and those already on inhaled steroids.	question 1.6) and the committee will consider those factors which affect FeNO levels, such as smoking, when addressing the question. People who are already on inhaled steroids have already received a diagnosis (or at least a provisional diagnosis) and how to proceed if there is now diagnostic doubt will vary depending on the pre-treatment evidence for asthma and the severity and nature of symptoms. It will not be possible to cover all these situations but the committee will consider them when reviewing the current recommendations on reducing maintenance treatment and on referral.
University Hospitals Birmingham NHS Foundation Trust	General	General	Issue of step one asthma large NICE still advocating SABA use as first line whilst BTS starting with ICS. This is major point and the two guidelines need to align with GINA guidelines advocating the use of ICS/Formeterol as preventer and reliever and should explore the use of this combined inhaler on demand bases in early/step one disease.	Thank you for your comment. First-line therapy is included in the scope of this guideline (draft question 3.1).
University Hospitals Birmingham NHS	General	General	Treatment: adherence assessment and place of smart inhalers.	Thank you for your comment. We are unaware of any new evidence that would change the recommendations on adherence assessment with the possible exception of work on smart inhalers. A question on this has been added to

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Foundation Trust				the scope. The recommendations in both guidelines will be editorially refreshed and aligned.

[i] https://erj.ersjournals.com/content/53/4/1802130.short
[ii] Royal College of Physicians (2014), *Why asthma still kills: The National Review of Asthma Deaths (NRAD)*. Available from: https://www.rcplondon.ac.uk/projects/outputs/why-asthma-still-kills
[iii] Stanford RH, Shah MB, D'Souza AO, Dhamane AD, Schatz M. *Short-acting β-agonist use and its ability to predict future asthma-related outcomes*. Ann Allergy Asthma Immunol. 2012 Dec;109(6):403-7. doi: 10.1016/j.anai.2012.08.014. Epub 2012 Oct 1. PMID: 23176877.
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[vi] Dissanayake SB. *Safety of beta2-agonists in asthma: linking mechanisms, meta-analyses and regulatory practice*. AAPS J 2015; 17: 754–757.
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[viii] Hancox RJ, Cowan JO, Flannery EM, Herbison GP, McLachlan CR, Taylor DR. *Bronchodilator tolerance and rebound bronchoconstriction during regular inhaled beta-agonist treatment*. Respir Med. 2000 Aug;94(8):767-71. doi: 10.1053/rmed.2000.0820. PMID: 10955752.

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[x] https://erj.ersjournals.com/lens/erj/55/4/1901872#content/figure_reference_6 >
[xi] Wraight JM, Smith AD, Cowan JO, Flannery EM, Herbison GP, Taylor DR. *Adverse effects of short-acting beta-agonists: Potential impact when anti-inflammatory therapy is inadequate*. Respirology. 2004 Jun 1;9(2):215–21. <https://onlinelibrary.wiley.com/doi/pdf/10.1111/j.1440-1843.2004.00557.x>
[xii] Annual Asthma Survey 2020 (unpublished data, available on request)
[xiii] Pavord ID, Beasley R, Agusti A, Anderson GP, Bel E, Brusselle G, et al. After asthma: redefining airways diseases. The Lancet. 2018 Jan 27;391(10118):350–400.
[xiv] https://link.springer.com/article/10.1007/s12325-020-01233-0
[xv] https://ginasthma.org/pocket-guide-for-asthma-management-and-prevention/
[xvi] https://www.cochranelibrary.com/cdsr/doi/10.1002/14651858.CD013518.pub2/full
[xvii] Foster JM, Beasley R, Braithwaite I, et al. *Patient experiences of as-needed budesonide-formoterol by Turbuhaler® for treatment of mild asthma; a qualitative study*. Respiratory Medicine. 2020 Dec;175:106154. DOI: 10.1016/j.rmed.2020.106154.
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[xxii] Asthma UK (2019), Living in Limbo: the scale of unmet need in difficult/severe asthma. Available from: https://www.asthma.org.uk/support-us/campaigns/publications/living-in-limbo/
[xxiii] ibid

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