

Council for Medical Schemes

Prescribed Minimum Benefits (PMB) Definition Guideline

Asthma

Document Information

Status	Final Draft (Version – V01)	*01 November 2026*
Prepared by	Clinical Advisory Committee (CAC) / Technical Working Group	*25 August 2026*
Reviewed by	*[external reviewers — to be populated once external review (Item 28) is complete]*	*[date]*
Approved by	*CMS Clinical/Technical Committee, then CMS Executive or Board*	*[to be completed on ratification]*

*This guideline will be submitted to [CMS governance body] for formal approval following completion of external review; the approval date and ratified version number will be recorded here upon sign-off.

Prescribed Minimum Benefits (PMB) Definition Guideline

Asthma

An adapted guideline — adopted, adapted and de novo recommendations developed from GINA 2025, NICE NG245, NDoH STG/EML 2024, BTS/SIGN and NAEPP 2020 using GRADE-ADOLOPMENT

Guidance for the Assessment and Management of Asthma in South Africa

Alignment: GINA 2025 | NICE NG245 (2024) | NDoH STG/EML 2024 | BTS/SIGN | NAEPP 2020

Disclaimer:

This Asthma PMB Definition Guideline defines the benefit entitlements and standards of care for the assessment, diagnosis, treatment, monitoring and management of asthma within the Prescribed Minimum Benefits (PMB) framework.

The recommendations describe the defined benefit entitlement for beneficiaries who meet the PMB criteria. They do not describe the full range of investigations, treatments or services that may be clinically indicated in individual cases, particularly where there is diagnostic uncertainty, severe asthma, difficult-to-treat asthma, significant comorbidities or other complex clinical circumstances.

Cases that fall outside the scope of this guideline remain subject to the applicable provisions of the Medical Schemes Act, 1998 (Act No. 131 of 1998), and its Regulations. Accordingly, this guideline should not be interpreted as limiting access to additional clinically appropriate healthcare services where these are required in terms of the Act.

This guideline forms part of the broader PMB policy and regulatory framework.

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Funding

This guideline was developed and funded by the Council for Medical Schemes as part of its statutory Prescribed Minimum Benefit review function. No pharmaceutical, medical device, or medical scheme industry funding was received for its development. Funding of the source guidelines is disclosed in their respective publications: GINA; NICE NG245 (NHS England, via NICE's standard public funding model); NAEPP 2020 (US National Heart, Lung, and Blood Institute); BTS/SIGN (professional-society funded); CTS 2021 (Canadian Thoracic Society, professional-society funded

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Introduction and Scope

The legislation governing the provision of Prescribed Minimum Benefits (PMBs) is contained in the Regulations enacted under the Medical Schemes Act, 1998 (Act No. 131 of 1998). A clearly defined statement of benefit entitlements may support consistent interpretation by beneficiaries, healthcare professionals and medical schemes. Variation in interpretation of asthma benefits has resulted in uncertainty regarding objective diagnosis, controller therapy, acute exacerbation care, follow-up and severe asthma escalation.

This guideline defines the minimum PMB-level standard for the assessment, diagnosis, treatment, monitoring and long-term management of asthma across all age groups. It is aligned with the CMS PMB Definition Project and with contemporary asthma care, particularly the shift away from SABA-only treatment and toward ICS-containing, risk-based and algorithmic management.

The methodological basis for the guideline is the CMS PMB Definition Project framework. Recommendation development and contextualisation were informed by the GRADE Handbook and the GRADE-ADOLOPMENT approach, including explicit Evidence-to-Decision considerations for benefits and harms, certainty of evidence, values and preferences, equity, resources, acceptability and feasibility [10-13]. The guideline was developed using the CMS PMB Definition Project methodology and the internationally recognised GRADE-ADOLOPMENT framework.

The objectives include defining PMB benefits, supporting consistent funding decisions and describing evidence-informed standards of asthma care within the PMB framework.

Unlike GINA, NICE, NAEPP and BTS/SIGN, whose primary aim is to guide individual clinical decision-making, this guideline's primary aim is to define funded PMB entitlements under the Medical Schemes Act; source recommendations were therefore selectively adopted or adapted only where relevant to PMB benefit definition, not reproduced as complete clinical guidance.

The appendices provide the supporting scope, methodology, Evidence-to-Decision framework, recommendation tables, algorithms and implementation tools.

Acknowledgements

The Council for Medical Schemes acknowledges the contribution of the Clinical Advisory Committee, Technical Working Group, methodological support team, clinical experts, medical scheme and administrator representatives, patient/caregiver representatives and other stakeholders who contributed to the asthma PMB definition process. Their input informed the evidence review, contextualisation, voting process and refinement of PMB boundaries.

The guideline reflects a multidisciplinary effort across pulmonology, paediatrics, primary care, emergency medicine, pharmacy, nursing, physiotherapy, occupational/environmental health, allergy/immunology, health economics, methodology and policy implementation.

Executive Summary

Asthma is a heterogeneous chronic inflammatory airway disorder characterised by variable respiratory symptoms and variable expiratory airflow limitation. It affects children, adolescents and adults, and may be presented as allergic, non-allergic, occupational, exercise-induced, obesity-related, cough-predominant or eosinophilic disease. Asthma exacerbations are potentially life-threatening and require timely recognition, evidence-based assessment and prompt treatment.

The principal policy shift in this guideline is that SABA-only therapy no longer constitutes the minimum PMB benefit standard for confirmed asthma. Inhaled corticosteroid (ICS)-containing therapy now forms the foundation of PMB-level asthma care, aligning the PMB framework with contemporary evidence and international best practice, while reflecting the demonstrated reduction in severe exacerbations and asthma-related mortality associated with ICS-containing treatment. The management framework uses an algorithmic escalation and de-escalation model based on control, risk, treatment intensity, age and feasibility. The guidelines were developed using the GRADE-ADOLOPMENT approach. Existing source guidelines meeting the predefined eligibility and appraisal criteria were identified, then synthesised and contextualised for South African PMB decision-making, and classified as Adopt, Adapt, Add/de novo or exclude. Recommendations were considered through an Evidence-to-Decision framework addressing benefits and harms, certainty of evidence, values and preferences, equity, resource use and affordability, acceptability and feasibility [10-13]. The recommendations are intended to define PMB benefit entitlements while supporting clinically appropriate, evidence-informed management, reducing preventable exacerbations and improving outcomes for beneficiaries with asthma. The recommendations define minimum PMB benefit entitlements while promoting evidence-informed, equitable and clinically appropriate asthma care that reduces preventable exacerbations and improves health outcomes.

Executive summary of PMB positions

Key policy change: SABA-only therapy no longer constitutes the PMB standard of care for confirmed asthma. All confirmed asthma requires an ICS-containing treatment strategy.

Policy area	Adopted PMB position
Diagnosis	Asthma diagnosis should be based on compatible clinical symptoms and objective evidence of variable expiratory airflow limitation, when objective testing is feasible.
Prevention and Risk Reduction	Preventive care should be individualised according to the patient's phenotype, risk factors, environmental exposures and comorbidities. Standard PMB care includes smoking and vaping cessation support, trigger assessment, vaccination review, written asthma action plans, patient education, inhaler technique assessment and adherence support.
Pharmacology Pharmacological Management	All patients with confirmed asthma require an ICS-containing treatment strategy. ICS-formoterol reliever and controller regimens are the preferred treatment pathway where clinically appropriate, taking into account age, indication, availability and formulary considerations.
Monitoring	Routine reviews include assessment of symptom control, future risk, reliever use, adherence, inhaler technique, comorbidities and lung function where feasible.
Exacerbations	Acute asthma exacerbations constitute PMB emergency care and include timely assessment, oxygen where indicated, inhaled bronchodilators, systemic corticosteroids, escalation of care and appropriate discharge planning with follow-up
Difficult-to-Treat and Severe asthma	Patients meeting the defined referral criteria should undergo specialist assessment and phenotype evaluation. High-cost therapies, including biologics,

Policy area	Adopted PMB position
	should be considered only in patients meeting clearly defined eligibility, response assessment and funding criteria.

Guidance for the Assessment and Management of Asthma

1. Assessment and Diagnosis

Asthma diagnosis requires a compatible clinical history and, wherever feasible, objective evidence of variable expiratory airflow limitation. Where objective testing is not immediately available, treatment may be initiated on clinical grounds while arrangements are made to confirm the diagnosis. Biomarkers, including fractional exhaled nitric oxide (FeNO) and blood eosinophil counts, may support the likelihood of Type 2 inflammation or corticosteroid responsiveness but do not independently confirm or exclude the diagnosis of asthma.

1.1 Diagnosis in primary care

- It is recommended that the primary care assessment include a structured history of respiratory symptoms, symptom variability, triggers, and risk factors. Typical symptoms include wheeze, cough, chest tightness and shortness of breath, particularly when variable or occurring at night or in the early morning.
- Document triggers such as exercise, viral infection, allergens, cold air, occupational exposure, tobacco/vaping, and biomass smoke.
- Objective evidence of variable airflow limitation should be demonstrated using spirometry with bronchodilator reversibility where available. Peak expiratory flow (PEF) monitoring may be used when spirometry is unavailable or delayed.
- A long-term diagnosis of asthma should be supported by documented objective evidence wherever feasible. Where objective testing cannot be performed, the clinical justification for diagnosis and treatment should be clearly documented.
- Children under 5 years may require a monitored therapeutic trial and diagnostic review when objective testing becomes feasible. In children younger than 5 years, where objective testing is generally not feasible, a monitored therapeutic trial followed by a diagnostic review is appropriate.

1.2 History and examination

- Symptom pattern, variability, triggers, and seasonality.
- Exacerbation history, emergency visits, hospitalisation, ICU admission, and intubation. Previous intubation or mechanical ventilation
- Medication history, SABA canister count, adherence and inhaler technique. SABA canister use, reliever overuse (where applicable)
- Comorbidities: rhinitis/sinusitis, GERD, obesity, OSA, anxiety/depression and smoking/vaping exposure.
- Occupational and environmental history. Respiratory sensitising agents or irritants
- Clinical examination should assess respiratory status and exclude alternative diagnoses. A normal examination does not exclude asthma.

1.3 Baseline investigations

Table 1. Baseline and diagnostic investigations

Investigation/assessment	PMB-level indication
Spirometry with bronchodilator reversibility	Preferred objective test to confirm the diagnosis of asthma where available and clinically feasible.
Peak expiratory flow (PEF) monitoring	Alternative objective assessment when spirometry is unavailable or delayed. Measurements should be performed using the same meter with a recorded diary over an appropriate monitoring period.
Pulse oximetry	Recommended in patients presenting with acute exacerbations, severe symptoms or suspected hypoxaemia.
FeNO / blood eosinophils: Fractional exhaled nitric oxide (FeNO) and/or blood eosinophil count	Adjunctive investigations that may assist assessment of Type 2 inflammation, phenotyping and treatment decisions in selected patients. They are not required for the routine diagnosis or monitoring of asthma in primary care.
Allergy testing	Selected patients with an allergic phenotype or where immunotherapy, biologic therapy or other management decisions may be influenced by the results. Consider in selected patients with suspected allergic asthma where the results are likely to influence allergen avoidance strategies, immunotherapy or biologic therapy.
Chest X-ray / ECG / additional tests: Chest radiograph, ECG and other investigations	Only when alternative diagnosis, complication or comorbidity is suspected. Not routinely indicated. Perform only when an alternative diagnosis, complication or clinically significant comorbidity is suspected.
Lung function monitoring	Repeat spirometry where available to confirm diagnosis, establish baseline function, assess response to treatment and monitor disease progression where clinically indicated.

1.4 Differential diagnosis

Alternative or coexisting diagnoses should be considered when symptoms are atypical, objective evidence of variable airflow limitation is absent, lung function is normal despite significant symptoms, or there is a poor response to appropriate asthma therapy. Important differential diagnoses include chronic obstructive pulmonary disease (COPD), heart failure, bronchiectasis, inducible laryngeal obstruction (vocal cord dysfunction), dysfunctional breathing, foreign body aspiration, pulmonary embolism, cystic fibrosis, recurrent aspiration, tracheobronchomalacia (airway malacia), chronic respiratory infection, **upper airway cough syndrome (postnasal drip), post-infectious cough**, and other respiratory or cardiovascular condition, as clinically indicated.

1.5 Phenotypes and endotypes

Table 2. Asthma phenotypes and implications for management - Asthma Phenotypes and Endotypes Relevant to PMB Management

Phenotype/endotype PMB Relevance	Clinical relevance
Allergic/atopic asthma	Often childhood onset, associated with allergic sensitisation and rhinitis/eczema; typically, ICS responsive. Often begins in childhood and is associated with allergic sensitisation, allergic rhinitis and/or eczema. Usually responds well to inhaled corticosteroid (ICS)-containing therapy.
Non-allergic asthma	Often adult onset with variable inflammatory pattern and variable corticosteroid response may demonstrate reduced responsiveness to corticosteroids.
Occupational asthma	Early identification and appropriate referral are important to prevent ongoing exposure, progressive disease and avoidable disability. Early recognition, exposure assessment and specialist referral are important to prevent ongoing exposure, progressive disease and avoidable disability.
Exercise-induced bronchoconstriction	Symptoms during or after exercise; optimise controller therapy and pre-exercise strategy.
Obesity-related asthma	Higher symptom burden and reduced steroid responsiveness; optimise asthma management and address weight-related factors where clinically appropriate. Often associated with increased symptom burden and reduced treatment responsiveness. Optimise asthma management and address weight-related factors where clinically appropriate.
Type 2-high/eosinophilic asthma	Elevated eosinophils and/or FeNO. Evidence of Type 2 inflammation (e.g. elevated blood eosinophils and/or FeNO) may respond to corticosteroids and biologics.
Type 2-low asthma	May be neutrophilic or paucigranulocytic; associated with smoking, pollution or obesity. May be neutrophilic or paucigranulocytic and is often associated with smoking, air pollution or obesity. Response to corticosteroid therapy may be reduced.
Cough-variant asthma	Presents predominantly with chronic cough without prominent wheeze. Diagnosis should be confirmed objectively where feasible before long-term treatment.

1.6 Links to appendices

See Appendix F: Diagnostic and Treatment Algorithms

2. Prevention and Risk Reduction

Prevention and risk reduction form integral components of asthma management within the PMB framework. Preventive interventions should be individualised according to the patient's phenotype, environmental exposures, comorbidities and future risk of exacerbations. Environmental interventions should be targeted to clinically relevant exposures or sensitisation, as broad environmental measures are unlikely to provide meaningful benefit in the absence of identified triggers.

- Smoking, cannabis and vaping cessation, including avoidance of secondhand exposure. Smoking cessation, avoidance of tobacco smoke exposure, cannabis smoking and vaping cessation.
- Assessment and mitigation of indoor allergens and irritants where clinically relevant. Assessment and reduction of clinically relevant indoor allergens and environmental irritants.
- Review of vaccination status and recommendation of influenza and other respiratory vaccines in accordance with national policy and individual clinical risk. Review vaccination status and recommend influenza and other respiratory vaccinations in accordance with national policy and individual clinical risk.
- Recognition of occupational exposures and referral where work-related asthma is suspected.
- Identify and appropriately manage or refer comorbidities that adversely affect asthma control, including allergic rhinitis, chronic rhinosinusitis, GERD, obesity, obstructive sleep apnoea and mental health conditions.
- Written asthma action plans, self-management education, inhaler technique assessment and adherence support. Regular assessment of inhaler adherence and inhaler technique at every appropriate clinical review.

3. Pharmacologic Management

It is recommended that all patients with confirmed asthma should receive an inhaled corticosteroid (ICS)-containing treatment regimen. **SABA-only therapy is no longer included in the minimum PMB standard of long-term asthma management**. Pharmacological treatment should be individualised and adjusted based on symptom control, future risk, age, treatment response, and patient preference, after assessing adherence, inhaler technique, environmental exposures, and comorbidities.

3.1 Core principles

- Use ICS-containing therapy at every level of care. All patients with confirmed asthma should receive an ICS-containing treatment strategy.
- Prefer ICS-formoterol reliever/controller strategies where clinically appropriate, age-appropriate and available within the applicable formulary. Where clinically appropriate, ICS-formoterol reliever/controller strategies (AIR/MART, according to approved indications) are the preferred treatment approach, subject to age, availability and formulary considerations.

- Within the Track 2 pathway, SABA use is paired with an ICS-containing treatment strategy.
- LABA monotherapy and routine oral beta-agonist therapy are not included in the recommended chronic asthma-treatment pathway. Where Track 2 therapy is used, every SABA dose should be accompanied by ICS-containing therapy.

Step-down may be considered after a sustained period of asthma control, with continued monitoring and without abrupt ICS withdrawal. Consider step-down after at least 2–3 months of sustained asthma control, with continued monitoring and without abrupt withdrawal of ICS therapy.

3.2 Escalation and de-escalation

SABA-only therapy no longer constitutes the minimum PMB standard of care for confirmed asthma. All patients with confirmed asthma require an ICS-containing treatment strategy.

Table 3. Algorithmic pharmacologic management principles

Clinical state	Required action
Newly diagnosed age >=12	Initiate an ICS-formoterol anti-inflammatory reliever strategy where appropriate. Where this is unavailable or unsuitable, initiate daily low-dose ICS with an appropriate reliever.
Poor control on initial therapy	Before stepping up therapy, confirm the diagnosis and assess adherence, inhaler technique, environmental exposures and comorbidities. Escalate to low-dose MART where appropriate.
Poor control on low-dose MART	Increase to medium-dose MART or add-on therapy according to pathway.
Persistent uncontrolled asthma	Reassess the diagnosis, adherence, inhaler technique, environmental exposures and comorbidities, optimise all modifiable factors, and consider specialist referral or advanced therapy where indicated.
Well controlled >=2-3 months	Consider step-down using the lowest effective ICS-containing regimen with close monitoring and action plan.

Before every treatment escalation, healthcare providers should confirm the diagnosis of asthma, assess adherence, review inhaler technique, identify modifiable environmental exposures, and optimise comorbid conditions.

3.3 Add-on and advanced therapies

LTRA, LAMA, specialist-supervised macrolide therapy and other add-on therapies may be considered in selected patients whose asthma remains inadequately controlled despite optimisation of standard therapy and management of modifiable risk factors.

Access to biologic therapies is determined using predefined eligibility, specialist-assessment, disease-severity and response-assessment criteria. **Leukotriene receptor antagonists (LTRAs), long-acting muscarinic antagonists (LAMAs), specialist-supervised macrolide therapy and other add-on therapies may be considered in selected patients whose asthma remains inadequately controlled despite optimisation of standard ICS-containing therapy, adherence, inhaler technique, environmental exposures and comorbidities.**

It is recommended that patients with suspected difficult-to-treat or severe asthma should be referred for specialist assessment. Biologic therapies should only be considered after confirmation of severe asthma, optimisation of

standard therapy and modifiable risk factors, assessment of exacerbation history, and phenotyping, including biomarker assessment where clinically appropriate and available.

It is recommended that biologic therapies, which are high-cost interventions, require explicit eligibility criteria, specialist assessment, response monitoring and clearly defined funding boundaries.

Before referral for biologic therapy, clinicians should confirm the diagnosis of asthma, optimise adherence and inhaler technique, address modifiable risk factors and comorbidities, and document exacerbation frequency and previous treatment response.

4. Monitoring and Long-Term Care

Asthma monitoring aims to optimise day-to-day symptom control, reduce future exacerbation risk, guide treatment adjustment and promote continuity of care. Routine monitoring should assess current symptom control, future risk, treatment response and the need for treatment adjustment.

Table 4. Standard Monitoring Schedule

Monitoring item	Minimum frequency/trigger
Symptom control and risk review	Every asthma visit.
Reliever use (including SABA overuse where applicable)	Every visit and through dispensing records where/if available.
Inhaler technique and adherence	At initiation, every review, and after device changes.
Lung function	At diagnosis, 3–6 months after initiating controller therapy, then every 1–2 years where feasible, or more frequently in patients at increased risk of exacerbations.
Comorbidities and exposures	Every routine review and before escalation.
Post-exacerbation review	Within 2–7 days following emergency department or hospital care, with a further review within 1–2 weeks where clinically indicated.
Written asthma action plan review Written asthma action plan	Frequency: At treatment initiation, following exacerbations and reviewed periodically during routine follow-up.
Need for treatment escalation or step-down	At every routine review, based on symptom control, exacerbation risk and adherence

5. Exacerbations

Asthma exacerbations are episodes of acute or subacute worsening of asthma symptoms and airflow limitation that require prompt recognition and treatment. The PMB pathway provides for timely emergency assessment, stabilisation and, where clinically indicated, hospital admission and inpatient management.

Table 5. Exacerbation severity classification

Severity	Clinical features	Objective criteria where available	Action
Mild-moderate	Wheeze, cough, dyspnoea; able to speak in phrases.	PEF >=50%; SpO2 >=94%.	Inhaled SABA via MDI with spacer (preferred where feasible) or nebuliser; consider early oral corticosteroids where clinically indicated; arrange early clinical review.
Severe	Marked breathlessness, accessory muscle use, unable to complete sentences.	PEF <50%; SpO2 <94%; tachypnoea/tachycardia.	Oxygen, repeated SABA, ipratropium, systemic corticosteroid, urgent transfer or observation.
Life-threatening	Silent chest, cyanosis, confusion, exhaustion, hypotension, bradycardia.	PEF <33%; SpO2 <92%; rising PaCO2.	Hospital/ICU management, IV magnesium, ventilatory support and senior review, and immediate senior clinician involvement

- Assess severity while starting treatment.
- Supplemental oxygen should be administered to patients with hypoxaemia and titrated to maintain an oxygen saturation of approximately 93–95% in adults and adolescents (94–98% in children where appropriate). Initial bronchodilator therapy should consist of inhaled SABA delivered via MDI with spacer (preferred where appropriate) or nebuliser, according to clinical severity and available resources.
- Add ipratropium for moderate-to-severe or poorly responsive attacks.
- Systemic corticosteroids are initiated early in patients meeting the specified clinical criteria. Sedative medicines are not routinely included in the management of an acute asthma exacerbation because of the associated respiratory risk. Sedative medications (including benzodiazepines) should not be routinely administered during an acute asthma exacerbation because of the risk of respiratory depression.
- Antibiotics, chest radiography and blood-gas testing are reserved for patients with specified indications, atypical features, severe disease or suspected complications. Antibiotics, chest radiography and arterial blood gas analysis should not be performed routinely and should be reserved for patients with specific clinical indications, atypical features, severe disease or suspected complications.

The discharge process includes review of controller therapy, inhaler technique, adherence, the written action plan - follow-up arrangements and assessment of ongoing need for ICS-containing therapy.

It is recommended that the he follow-up pathway provides for review within 2–7 days after an exacerbation, with earlier assessment for patients at higher clinical risk.

EMS/prehospital care: Severe and life-threatening exacerbations may require emergency medical services and urgent transfer to an appropriate level of care. **Emergency medical services (EMS): Patients with severe or life-threatening exacerbations should be transported urgently to an appropriate level of care while receiving prehospital emergency management where available. Emergency assessment and stabilisation of acute asthma exacerbations constitute PMB emergency medical care.**

6. Specialist and Severe Asthma Care

6.1. Specialist Referral and Severe Asthma Care

Difficult-to-treat asthma refers to asthma that remains poorly controlled despite medium- or high-dose ICS-containing therapy, or that is associated with frequent exacerbations, often because of potentially modifiable factors such as poor adherence, incorrect inhaler technique, ongoing environmental exposures or untreated comorbidities.

Severe asthma is asthma that remains uncontrolled despite adherence to optimised high-dose ICS-containing therapy and management of contributory factors, or that requires high-dose therapy to maintain control.

Patients meeting the criteria for difficult-to-treat or severe asthma should be referred for specialist assessment.

- The severe-asthma assessment includes confirmation of the asthma diagnosis
- Objectively assess lung function and variability.
- Adherence and inhaler technique are assessed as part of the severe-asthma evaluation.
- Environmental and occupational exposures and relevant comorbidities are assessed and managed or referred as clinically indicated.
- Assess exacerbation frequency and oral corticosteroid exposure.
- Assess Type 2 inflammatory markers, including eosinophils, FeNO and allergic sensitisation; when clinically indicated and available
- Evaluate add-on therapy including LAMA and selected specialist options.
- Specialist assessment is included for patients meeting the referral criteria for difficult-to-treat or severe asthma.
- Confirm the diagnosis of asthma using objective evidence where feasible.
- Assess lung function and document variable expiratory airflow limitation.
- Review adherence to prescribed treatment and inhaler technique.
- Assess environmental, occupational and lifestyle exposures.
- Identify and optimise comorbidities that may contribute to poor asthma control.
- Document exacerbation frequency, hospitalisations and cumulative oral corticosteroid exposure.

- Perform phenotyping, including assessment of Type 2 inflammatory markers (e.g. blood eosinophils, FeNO and allergic sensitisation), when clinically indicated and available.
- Evaluate eligibility for add-on therapies, including LAMA and other specialist-directed therapies.
- Specialist assessment is recommended for all patients meeting the defined referral criteria for difficult-to-treat or severe asthma.
- Consider biologic therapy only after confirmation of severe asthma and fulfilment of defined clinical and PMB eligibility criteria.
- Long-term maintenance oral corticosteroid therapy should be avoided where possible because of the risk of significant adverse effects. Patients requiring repeated or maintenance oral corticosteroids should be considered for specialist assessment.

Refer if:

- ≥2 exacerbations/year

- Diagnostic uncertainty

- Persistent uncontrolled asthma despite Step 4/5 therapy
- Suspected biologic eligibility

It is recommended biologic therapy is considered following specialist assessment, confirmation of severe asthma and evaluation against the specified eligibility criteria. Use should be guided by clearly defined eligibility criteria, objective evidence of disease severity, phenotype assessment, response evaluation, stopping criteria and funding parameters within the PMB framework.

- Inclusion of biologic therapies in the clinical pathway is distinct from determination of PMB funding entitlement, which is governed by the applicable eligibility and funding criteria. Written asthma action plans.

7. Non-Pharmacologic Management Patient Education and Non-Pharmacological Management

Non-pharmacological interventions form an integral component of comprehensive asthma care and should be individualised according to the patient's clinical needs, risk factors and comorbidities.

- Inhaler technique training and spacers where appropriate.
- Adherence support and refill monitoring.
- Smoking/vaping cessation.
- Trigger identification and mitigation.
- Consider physiotherapy referral for patients with dysfunctional breathing, physical deconditioning, persistent dyspnoea or prolonged recovery following an exacerbation.

- Weight-related factors and physical activity are assessed, with intervention or referral where clinically indicated. Assess weight-related factors and physical activity, with intervention or referral where clinically indicated
- Psychosocial assessment and identification of barriers to self-management, including health literacy, anxiety and depression, with referral or management as clinically appropriate. Assess psychosocial factors that may impair asthma control or self-management, including health literacy, anxiety and depression, with appropriate intervention or referral where indicated.
- Shared decision-making and patient education should support self-management, treatment adherence and appropriate use of the written asthma action plan.

Non-pharmacological interventions form an integral component of comprehensive asthma care and should be individualised according to the patient's clinical needs, risk factors and comorbidities.

- Written asthma action plans.
- Inhaler technique training and spacer use where appropriate.
- Adherence support and refill monitoring.
- Smoking, vaping and cannabis cessation.
- Trigger identification and mitigation.
- Physiotherapy referral where clinically indicated.
- Weight management and physical activity.
- Psychosocial assessment and support.
- Shared decision-making and self-management education.
-

8. PMB Package and Care Pathways: PMB Benefit Package and Service Delivery Pathway

The PMB package defines the minimum benefit entitlements and service functions expected at each level of care. Most patients with asthma can be assessed and managed within primary care, while referral to higher levels of care should be guided by predefined clinical criteria.

Referral should be considered for diagnostic uncertainty, severe or recurrent exacerbations, persistent poor control despite optimised therapy, suspected occupational asthma, suspected difficult-to-treat or severe asthma, or where specialist assessment is required.

Table 6. PMB service architecture

Care level	Minimum PMB service functions
Primary care= **default level of care**	Clinical assessment and diagnosis; objective confirmation where feasible; initiation and optimisation of ICS-containing therapy; routine monitoring; inhaler technique assessment; written asthma action plans; self-management support; management of most patients with asthma, including mild-to-moderate exacerbations; and referral where clinically indicated.

Care level	Minimum PMB service functions
Secondary care= **complexity increases**	Comprehensive lung function assessment; treatment optimisation and step-up therapy; management of comorbidities; observation and management of moderate-to-severe exacerbations; and coordinated discharge planning and follow-up..
Tertiary care= specialist care	Specialist evaluation; phenotyping; assessment and management of difficult-to-treat and severe asthma; advanced diagnostics where available; multidisciplinary management; and care of high-risk exacerbations.
Quaternary care= **highly specialised services**	Complex severe asthma management, advanced immunomodulatory therapies, biologic therapy where eligibility and funding criteria are met, advanced airway diagnostics and specialised multidisciplinary support. Management of complex severe asthma; advanced immunomodulatory therapies; biologic therapy where PMB eligibility and funding criteria are met; specialised airway diagnostics; and multidisciplinary specialist support.

The majority of beneficiaries with asthma should be appropriately managed within primary care. Referral should be reserved for patients meeting predefined clinical criteria or requiring services unavailable at the current level of care. The PMB framework promotes management at the lowest appropriate level of care while ensuring timely referral for patients requiring more specialised assessment or treatment.

9. Special Populations and Clinical Circumstances

Table 7. Special population considerations

Population	Key PMB considerations
Children <5 years	Diagnosis is mainly clinical; use monitored therapeutic trial, caregiver education, spacer/facemask, vaccination and review when objective testing becomes possible. Diagnosis is primarily clinical. Management may include a monitored therapeutic trial of ICS where appropriate, caregiver education, correct spacer/facemask use, vaccination, and periodic diagnostic review when objective testing becomes feasible.
Children 5-16 years	Objective confirmation using spirometry with bronchodilator reversibility where feasible, or peak expiratory flow monitoring where appropriate. FeNO may be used as an adjunct where available. Ensure age-appropriate inhaler devices and provide caregiver and school asthma action plans.
Adolescents	Assess adherence, SABA overuse, psychosocial risk and exercise participation; avoid SABA-only management. Assess adherence, reliever overuse, psychosocial wellbeing and exercise participation; avoid SABA-only treatment.
Pregnancy/lactation	Continue or initiate ICS-containing therapy when indicated; uncontrolled asthma poses greater maternal-fetal risk than standard asthma medication. Continue or initiate ICS-containing therapy where indicated. Poorly controlled asthma presents a greater risk to both mother and fetus than recommended asthma medications.

Population	Key PMB considerations
Older adults	Assess fixed obstruction, COPD overlap, polypharmacy, device dexterity and comorbid cardiovascular disease. Assess inhaler technique and cognitive impairment where relevant.
Occupational asthma	. Document occupational exposures, consider serial peak expiratory flow measurements at and away from work, and arrange early specialist or occupational health referral where appropriate.
Patients with asthma-COPD overlap (ACO)	Consider alternative diagnoses, optimise inhaled therapy and manage both conditions according to clinical presentation.

Referral pathways are based on clinical need and complexity, and do not require sequential progression through every level of care.

10. Burden of Disease

The CAC classified asthma as a priority condition for PMB definition on the basis of its prevalence, morbidity, mortality, healthcare utilisation and potential for prevention and treatment. Asthma burden has been associated with delayed or inaccurate diagnosis, limited use of anti-inflammatory treatment, high reliever use, environmental exposures, comorbidities, adherence difficulties and unequal access to care. The Clinical Advisory Committee (CAC) identified asthma as a priority condition for PMB definition because of its high prevalence, associated morbidity and mortality, healthcare utilisation, and the potential to improve outcomes through timely diagnosis and evidence-based treatment. Effective implementation of evidence-based asthma care has the potential to reduce preventable exacerbations, emergency care utilisation, hospital admissions and asthma-related mortality while improving quality of life. Asthma-related morbidity and mortality remain influenced by delayed or inaccurate diagnosis, underuse of anti-inflammatory therapy, excessive reliever use, environmental exposures, comorbidities, poor adherence and inequitable access to care.

Compared with the populations and health systems addressed by [GINA 2025 / NICE NG245 / NAEPP 2020], South Africa's asthma burden differs in e.g., higher prevalence and mortality in low-income and under-resourced urban/rural populations; constrained primary-care access to spirometry and FeNO testing; differential inhaler/medicine availability across the public and private sectors]. These contextual differences directly informed [specify affected recommendation IDs, e.g., the alternative PEF-based diagnostic pathway in C-04].

Table 8. Burden and priority judgement: Not a clean Adopt — a real finding

Domain	PMB priority judgement
Epidemiology	Asthma affects all ages and is common in South Africa and globally. Asthma is a common chronic respiratory disease affecting children and adults in South Africa and globally, with a substantial impact on population health.
Morbidity/mortality	Many severe exacerbations, intensive care admissions and asthma-related deaths are potentially preventable through timely diagnosis, appropriate ICS-containing therapy and evidence-based management.
Economic burden	Costs arise from controller medicines, emergency care, hospitalisation . and indirect costs from lost productivity, absenteeism and reduced quality of life
Equity	Access gaps exist for objective diagnostic testing, controller medicines, spacers and specialist referral, with additional inequities in access to advanced severe asthma services and biologic therapies particularly for patients requiring specialist assessment and advanced therapies
Urgency	The CAC concluded that the available evidence supports a PMB framework centred on early diagnosis, ICS-containing therapy, prevention of exacerbations and risk-reduction strategies.
Health system impact	Asthma contributes substantially to primary care consultations, emergency department attendances, hospital admissions and healthcare utilisation, particularly when poorly controlled

Section 11: Limitations and Future Research

Limitations

This adaptation relied on the evidence syntheses and recommendations of five international source guidelines (GINA 2025, NICE NG245, BTS/SIGN, NHLBI/NAEPP 2020, CTS 2021) rather than an independent, de novo systematic review of primary evidence. Certainty is correspondingly lower, and CAC consensus was harder to reach, in the areas identified as key debated boundaries during Round 2 voting (Appendix D): allergen immunotherapy (subcutaneous and house dust mite sublingual), FeNO-guided titration and other advanced diagnostic investigations, bronchial challenge testing thresholds, biologic therapy eligibility, and physiotherapy/rehabilitation services.

For allergen immunotherapy specifically, this adaptation's current wording diverges from the cited NAEPP 2020 recommendation, which recommends **against** sublingual immunotherapy where this guideline presents it as an available option

(see Appendix E, rows A-12 and B-24) — a limitation that should be resolved by the CAC before this guideline reaches final publication.

South African-specific effectiveness and cost-effectiveness data are also limited for several advanced therapies addressed in this guideline, including biologic therapies (Domain F) and bronchial thermoplasty (F-05), where recommendations currently rely on international trial populations and cost contexts that may not directly reflect the South African medical schemes environment.

Future Research Priorities

Future research priorities specific to the South African context include:

1. Local severe-asthma phenotype prevalence data, to inform biologic eligibility criteria appropriate to the South African patient population.
2. Cost-effectiveness of MART/AIR (anti-inflammatory reliever) strategies within the South African EML/PMB funding context.
3. Evaluation of diagnostic-pathway performance — including the PEF-based alternative diagnostic pathway (C-04) — in settings where spirometry access is constrained.
4. Local evidence on allergen immunotherapy (subcutaneous and house dust mite sublingual) effectiveness and cost-effectiveness, to help resolve the current divergence from the cited NAEPP 2020 recommendation (A-12, B-24).

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ANNEXURE A

SCHEDULE OF MINIMUM PMB BENEFITS MEDICAL SCHEMES MUST FUND — ASTHMA

Purpose and interpretation

This Schedule specifies the minimum healthcare services, investigations, medicines, devices, monitoring and referral services that constitute the PMB benefit entitlement for a beneficiary with asthma, subject to the clinical indications, eligibility criteria and care pathways specified in this guideline.

A medical scheme must fund clinically appropriate services included in this Schedule where the beneficiary meets the applicable PMB and clinical criteria. The Schedule should be read together with the Medical Schemes Act, 1998, its Regulations and the detailed recommendations contained in this guideline.

The Schedule defines a minimum benefit entitlement and not an exhaustive list of all clinically appropriate care. Additional services may remain fundable where required by the Medical Schemes Act and Regulations or where clinically necessary in circumstances falling outside the defined pathway.

Table 1. Schedule of Minimum Asthma PMB Benefits

Benefit category	Minimum service/benefit to be funded	Funding indication / boundary	Expected level of care
1. Initial clinical assessment	Consultation; structured asthma history; physical examination; assessment of symptoms, variability, triggers, history of	Suspected or confirmed asthma	Primary care

	exacerbation, medication use, comorbidities and environmental/occupational exposures		
2. Objective diagnostic confirmation	Spirometry with bronchodilator reversibility	Where available and clinically feasible for diagnosis/confirmation	Primary/secondary care
	Peak expiratory flow monitoring, including appropriate monitoring/recording	Alternative where spirometry is unavailable, delayed or inappropriate	Primary care
3. Young children	Clinical assessment and monitored therapeutic trial where appropriate	Children <5 years where reliable objective testing is not feasible	Primary/paediatric care
4. Pulse oximetry	Measurement of oxygen saturation	Acute exacerbation, severe symptoms or suspected hypoxaemia	All appropriate levels
5. Additional diagnostic investigations	Chest radiograph, ECG and other clinically appropriate investigations	Only where alternative diagnosis, complication or clinically significant comorbidity is suspected	Appropriate level
6. Biomarkers/phenotyping	Blood eosinophil count and/or FeNO	Selected patients where results are expected to influence phenotyping or treatment decisions; not routine primary-care diagnosis or monitoring	Secondary/tertiary care
7. Allergy assessment	Clinically appropriate allergy testing	Selected patients with suspected allergic asthma where results are expected to influence avoidance strategies, immunotherapy or biologic-treatment decisions	Secondary/tertiary care
8. Controller pharmacotherapy	An **ICS-containing treatment regimen**	All beneficiaries with confirmed asthma	Primary care and above
9. Preferred reliever/controller pathway	ICS-formoterol anti-inflammatory reliever and/or MART strategy	Where clinically appropriate, age appropriate, indicated and available within the applicable formulary	Primary care and above

10. Alternative controller pathway	Daily low-dose ICS with an appropriate reliever	Where ICS-formoterol strategy is unavailable, unsuitable or otherwise not clinically appropriate	Primary care
11. Treatment escalation	Appropriate escalation of ICS-containing therapy, including low-/medium-dose MART or other guideline-supported controller escalation	Persistent inadequate control after confirmation of diagnosis and assessment of adherence, inhaler technique, exposures and comorbidities	Primary/secondary care
12. Add-on therapy	LTRA, LAMA and other guideline-supported add-on therapy	Selected patients remaining inadequately controlled despite optimised standard therapy	Primary/secondary/specialist care according to treatment
13. Inhaler administration devices	Appropriate inhaler device and spacer/facemask where clinically required	Where necessary for effective administration of funded inhaled treatment, including age-appropriate devices for children	All levels
14. Routine asthma monitoring	Assessment of symptom control, exacerbation risk, reliever use, adherence, inhaler technique, exposures, comorbidities and treatment response	At appropriate routine asthma reviews	Primary care
15. Lung-function monitoring	Repeat spirometry/lung-function assessment	At diagnosis; following initiation of controller treatment where indicated; periodically thereafter according to clinical risk and feasibility	Primary/secondary care
16. Written asthma action plan	Development, education and periodic review of an individual written asthma action plan	All patients where appropriate; particularly at treatment initiation and following exacerbations	Primary care and above
17. Self-management support	Asthma education, inhaler-technique training and adherence support	Routine component of asthma management	Primary care and above

18. Risk-factor modification	Smoking/vaping/cannabis cessation intervention; clinically relevant trigger and exposure assessment	Where relevant to asthma control or exacerbation risk	Primary care
19. Occupational asthma	Occupational exposure assessment, appropriate serial PEF where indicated and specialist/occupational-health referral	Suspected work-related asthma	Primary/secondary/specialist care
20. Comorbidity assessment	Assessment and clinically appropriate management/referral of relevant comorbidities	Where comorbidities adversely affect asthma diagnosis, control or treatment	Appropriate level
21. Mild-to-moderate exacerbation	Clinical assessment; inhaled bronchodilator treatment; systemic corticosteroid where indicated; monitoring and early review	Acute asthma exacerbation according to severity	Primary/emergency care
22. Severe exacerbation	Oxygen where hypoxaemic; repeated inhaled SABA; ipratropium; systemic corticosteroids; monitoring; observation; emergency transfer and/or admission where required	Severe acute exacerbation	Emergency/secondary care
23. Life-threatening exacerbation	Emergency stabilisation, hospitalisation, ICU assessment/care, IV magnesium where indicated, ventilatory support and senior/specialist review	Life-threatening asthma	Hospital/ICU
24. Emergency medical transport	Appropriate EMS assessment, stabilisation and urgent transfer	Severe or life-threatening exacerbation requiring transfer to an appropriate level of care	Prehospital/emergency care
25. Hospitalisation	Emergency department, observation, ward and/or ICU management as clinically indicated	Exacerbation requiring hospital-level management	Secondary/tertiary care

26. Post-exacerbation care	Review of controller therapy, adherence, inhaler technique and action plan, with appropriate follow-up	Following emergency department or hospital treatment; initial review generally within 2–7 days	Primary/specialist care
27. Specialist consultation	Specialist physician, pulmonology or paediatric respiratory assessment as appropriate	Diagnostic uncertainty; recurrent/severe exacerbations; persistent uncontrolled asthma despite optimised therapy; suspected occupational asthma; difficult-to-treat or severe asthma; or consideration of advanced therapy	Secondary/tertiary care
28. Severe-asthma assessment	Confirmation of diagnosis; lung-function assessment; adherence and inhaler-technique assessment; exposure and comorbidity review; exacerbation and corticosteroid history; appropriate phenotyping	Patients meeting difficult-to-treat/severe-asthma referral criteria	Specialist/tertiary care
29. Severe-asthma phenotyping	Eosinophils, FeNO, allergic sensitisation and other clinically indicated phenotype assessment	Where required to establish eligibility for advanced treatment	Specialist/tertiary care
30. Biologic therapy	Appropriate biologic treatment	Only where the beneficiary satisfies defined PMB clinical eligibility, severity, phenotype and prior-treatment criteria following specialist assessment	Tertiary/quaternary care
31. Biologic monitoring	Required clinical and laboratory assessment of treatment response and continued eligibility	Beneficiaries receiving PMB-funded biologic therapy	Specialist care
32. Other specialist-directed therapies	LAMA, selected specialist-supervised therapy and other guideline-supported advanced interventions	Where specified eligibility and clinical criteria are met	Specialist care

33. Physiotherapy/rehabilitative intervention	Appropriate physiotherapy assessment/intervention	Where clinically indicated for dysfunctional breathing, physical deconditioning, persistent dyspnoea or prolonged recovery following an exacerbation	Appropriate level
34. Psychosocial support/referral	Assessment and appropriate intervention/referral	Where psychosocial factors or health-literacy barriers materially impair asthma control or self-management	Appropriate level
35. Pregnancy and other special populations	Age- and circumstance-appropriate asthma assessment, treatment, monitoring and devices	According to the special-population recommendations in this guideline	Appropriate level

Mandatory minimum pharmacological principle

For confirmed asthma, SABA-only long-term treatment does not constitute the minimum PMB standard. The minimum funded pharmacological pathway must include an ICS-containing treatment strategy appropriate to the beneficiary's age, clinical status and treatment pathway.
Formulary arrangements may determine the clinically appropriate product funded within a therapeutic class, subject to the Medical Schemes Act, Regulations and applicable PMB requirements, but should not remove the underlying clinical benefit entitlement established by this Schedule.

Funding according to clinical need rather than predetermined setting

The level-of-care designation in this Schedule identifies the usual or most appropriate service-delivery setting and does not create an absolute funding restriction. A beneficiary may receive care at a higher level where required by clinical severity, complexity, availability of services, emergency circumstances or an appropriate referral pathway.
Primary care is the default level for most routine asthma management. Secondary, tertiary and quaternary services become part of the minimum PMB entitlement when the beneficiary meets the relevant clinical referral, severity or eligibility criteria.

Services not routinely included
The following are not routine minimum benefits for every beneficiary with asthma, but may become PMB-funded where the clinical indications specified in this guideline are met:

- FeNO and advanced biomarker testing;
- allergy testing;
- chest radiography and other additional diagnostic investigations;

- specialist assessment;
- advanced phenotyping;
- physiotherapy;
- advanced add-on therapies; and
- biologic therapy.

The fact that a service is not routinely indicated must not be interpreted as an absolute exclusion where the beneficiary satisfies the clinical criteria specified in this guideline.

Utilisation-management principle

Medical schemes may apply clinically appropriate managed-care measures consistent with the Medical Schemes Act and Regulations. Such arrangements should facilitate delivery of the defined PMB entitlement and should not substitute a materially inferior service where the beneficiary meets the clinical criteria for a benefit specified in this Schedule.

Minimum funding rule

For purposes of benefit administration, the funding question should therefore be:
"Does the beneficiary meet the clinical and PMB eligibility criteria for the service specified in this Schedule?"
rather than:
"Is the service routinely available to every beneficiary with asthma?"
Where the applicable criteria are met, the service forms part of the defined asthma PMB pathway, subject to the Medical Schemes Act and Regulations.

Appendices

The following appendices are part of the guideline and are internally hyperlinked from the main text. Full sortable recommendation and evidence tables are also provided in the companion spreadsheet artefacts.

Appendix A: Scope, Remit and Policy Context

This guideline applies to the assessment, diagnosis, treatment, monitoring and management of asthma across all age groups, including intermittent, mild, moderate and severe persistent asthma, as well as allergic, non-allergic, occupational and exercise-induced phenotypes. It also addresses the assessment and management of acute asthma exacerbations. Chronic obstructive pulmonary disease (COPD) and other irreversible chronic lung diseases are excluded, except where differentiation from asthma or consideration of overlap syndromes is clinically required.

This guideline defines minimum PMB standards of care and benefit entitlements. It does not preclude the provision or funding of additional clinically appropriate investigations, treatments or services where these are justified by individual patient circumstances and the applicable provisions of the Medical Schemes Act.

Scope element	Definition
Intended Users	*This guideline is intended for: (1) treating healthcare professionals (primary care providers, pulmonologists, paediatricians, emergency clinicians) managing patients with suspected or confirmed asthma; and (2) medical scheme clinical/case managers, funders and administrators responsible for PMB benefit adjudication. Unlike the source guidelines, which are written for clinicians only, this adapted guideline additionally serves a funding-adjudication audience.*
Population	Infants and young children with recurrent wheezing in whom asthma is suspected; children ≥5 years, adolescents and adults with suspected or confirmed asthma.
Settings	Primary, secondary, tertiary and quaternary care; emergency departments, outpatient clinics, prehospital/EMS and rehabilitation settings. *Unlike the source guidelines, which are primarily intended to guide clinical care and clinical decision-making, this adaptation also applies to medical scheme funding and case-management settings. These funding and benefit-management contexts fall outside the primary scope of GINA, NICE NG245, the NDoH STG/EML, BTS/SIGN and NAEPP and are therefore addressed explicitly in this adaptation.*
Interventions	Diagnosis, prevention, pharmacologic management, patient education, monitoring, acute exacerbation management, specialist care, non-pharmacologic interventions and rehabilitation.
Economic perspective	The guideline defines minimum PMB benefit entitlements to promote equitable, evidence-informed and sustainable access to clinically appropriate asthma care within the Medical Schemes Act and PMB framework.
Update cycle	At least every 3 years or earlier if major new evidence, medicines, safety concerns or policy changes arise.

Scope element	Definition
Purpose	To define the minimum PMB benefit entitlements and service standards for the assessment, diagnosis, treatment, monitoring and long-term management of asthma across the continuum of care.
Out of scope	Management of COPD without asthma, interstitial lung disease, bronchiectasis, cystic fibrosis and other chronic respiratory diseases, except where differentiation from asthma is required.

Appendix B

Name	Affiliation & discipline	Role	Responsibility
Adri Kok	Specialist Physician;SAPPF	CAC Chair	Chairs CAC deliberations and voting; final accountability for recommendation sign-off
Angelique Coetzee	General Practitioner, Private Practice	CAC member	Reviews evidence and votes on recommendations, particularly paediatric/adolescent domains
Brenda Morrow	Medical Doctor Primary Care Ethics;Public Sector	CAC member	Reviews evidence and votes on recommendations, particularly primary-care diagnostic and initial-treatment domains
Cathelijn Zeijlemake	Medical Doctor, Occupational Health;Private Healthcare	CAC member	Reviews evidence and votes on recommendations, particularly acute exacerbation and emergency-care domains
Jimmy Selesho	Medical Doctor;Administrator	CAC member	Reviews evidence and votes on recommendations, particularly medicine/formulary and PMB funding domains
Louise Wahl	Pharmacist;Mediscor	CAC member	Reviews evidence and votes on recommendations, particularly monitoring, education and self-management domains
Natheem Salie	Pharmacist;Momentum	CAC member	Reviews evidence and votes on recommendations, particularly monitoring, education and self-management domains
Nkateko Mathebula	Medical Doctor, Medscheme	Patient representative	Provides patient/caregiver perspective on values, preferences and acceptability of recommendations

Nonkqubela Mxoli	Specialist Nurse, GEMS	Secretariat	Project coordination, documentation, meeting logistics, and maintenance of the recommendation matrix
Mark Hyman	Patient Advocacy;Patient Advocacy	CAC member	Provides patient/caregiver perspective on values, preferences and acceptability of recommendations
Ameer Hohfeld	Methodologist, SAMRC	TWG methodologist	Leads evidence extraction, GRADE-ADOLOPMENT methodology, and preparation of the Evidence-to-Decision framework

CAC and TWG members were nominated by [relevant professional bodies, e.g., South African Thoracic Society, SA Academy of Family Practice] and appointed by CMS based on clinical/methodological expertise, sectoral representation and absence of material conflicts of interest (see Appendix — Declaration and Management of Interests)

Appendix B: Full GRADE-Adolopment Methodology

This guideline was developed using the GRADE-ADOLOPMENT methodology, which builds on high-quality existing clinical practice guidelines while contextualising recommendations for the South African PMB environment. The CMS PMB Definition Project framework provided the policy foundation for defining minimum benefit entitlements, taking into account clinical effectiveness, cost-effectiveness, affordability and the financial sustainability of medical schemes. Candidate recommendations were extracted, synthesised and mapped to predefined asthma domains before review by the Clinical Advisory Committee (CAC) [10-13].

Methodological source framework

- **CMS PMB Definition Project framework:** Defines the PMB policy framework and requires consideration of clinical effectiveness, cost-effectiveness, affordability and the financial sustainability of medical schemes. Defines the purpose of benefit definitions and requires consideration of clinical effectiveness, cost-effectiveness, affordability and scheme financial viability [10].
- **GRADE Handbook:** provides the structured approach for rating certainty of evidence and moving transparently from evidence to recommendations [11].
- **GRADE-ADOLOPMENT guidance:** provides the method for adopting, adapting or developing contextualised recommendations and for documenting Evidence-to-Decision judgements [12,13].

1. Source guideline identification: GINA, NICE NG245/BTS/SIGN, NAEPP 2020, CTS 2021, NDoH STG/EML and relevant systematic reviews.
2. Recommendation extraction and deduplication into a Table of Recommendations. Extraction, consolidation and deduplication of recommendations into a master Table of Recommendations. For each candidate recommendation, the TWG extracted the source guideline's recommendation wording, its stated certainty-of-evidence rating (where reported) and its supporting rationale. This information was presented to the CAC alongside the PMB Evidence-to-Decision considerations (Appendix C) to inform the Adopt/Adapt/Add-de novo/Exclude vote.
3. Assessment of guideline credibility, currency, applicability and overlap.
4. Contextualisation addressed the South African healthcare setting, resource availability, affordability, referral pathways and PMB benefit-entitlement requirements.
5. CAC review with independent voting to classify recommendations as Adopt, Adapt, Add/de novo, Exclude or Requires Further Discussion
6. Consensus deliberation for non-consensus items and second-round voting.
7. Final wording and definition of PMB benefit boundaries informed by clinical evidence, patient benefit, implementation feasibility, equity considerations and responsible resource utilisation.

Decision	Meaning
Adopt	Use the source recommendation verbatim or with minor clarifications only, without altering clinical intent.
Adapt	Modify the recommendation to reflect the South African healthcare context, feasibility, affordability, implementation requirements or PMB benefit boundaries, while preserving the underlying clinical intent.
Add / de novo	Develop a new recommendation to fill a South African-specific gap such as referral steps, discharge bundles or PMB service definitions.

Decision	Meaning
Exclude	Omit recommendations that are outside the scope of the guideline, incompatible with the PMB framework, unsupported by the available evidence, or not applicable to the intended level of care.

Recommendations were assessed using an Evidence-to-Decision framework consistent with GRADE methodology [11-13]. The framework considered benefits and harms, certainty of evidence, equity, feasibility, resource implications and affordability, and acceptability to stakeholders. Each recommendation was considered using an Evidence-to-Decision (EtD) framework consistent with GRADE methodology. Judgements incorporated the balance of benefits and harms, certainty of evidence, equity, feasibility, resource implications, affordability and stakeholder acceptability. The certainty of evidence and the strength of recommendations were considered separately during deliberations.

No independent systematic literature search was conducted for this adaptation. All recommendations are based on the evidence syntheses already performed by the five named source guidelines (search/evidence dates as reported by each source); no additional primary research was separately identified or incorporated.

Evidence

↓

Existing Guidelines

↓

Recommendation Extraction

↓

GRADE-ADOLOPMENT

↓

Evidence-to-Decision

↓

CAC Voting

↓

Consensus

↓

PMB Recommendation

Source guidelines were selected based on methodological quality, currency, international credibility and relevance to PMB decision-making.

Source guidelines were eligible for inclusion if: (1) published or last updated within 5 years; (2) developed using a transparent, evidence-based methodology; (3) issued by an internationally recognised professional or governmental body; and (4) relevant

to asthma diagnosis or management across the lifespan. [If used:] Methodological quality was appraised using the AGREE II instrument; guidelines are summarised in Appendix B, Table [x].

The purpose of the GRADE-ADOLOPMENT process was not to reproduce existing international guidelines, but to develop evidence-informed recommendations that are appropriate, feasible and sustainable within the South African PMB environment.

The developers of the source guidelines were not directly contacted during this adaptation; all recommendations, evidence tables and rationale were drawn from each guideline's publicly available published documents and supplementary materials.

Appendix C: Evidence-to-Decision Framework

The Clinical Advisory Committee applied the GRADE Evidence-to-Decision framework when considering whether recommendations should be incorporated into the PMB definition guideline. Judgements addressed safety and efficacy, certainty of evidence, patient values and preferences, equity, affordability and resource use, feasibility and acceptability. These criteria were considered alongside clinical need, implementation constraints and the objectives of the PMB framework [11-13]. The Clinical Advisory Committee (CAC) applied the GRADE Evidence-to-Decision (EtD) framework when determining whether recommendations should be incorporated into the PMB Definition Guideline. Judgements considered the balance of benefits and harms, certainty of the evidence, patient values and preferences, equity, resource implications, affordability, feasibility and stakeholder acceptability. These considerations were interpreted within the legislative and policy objectives of the Medical Schemes Act and the PMB framework.

EtD axis/domain	Question asked by the panel; Question considered	PMB implication
Safety and efficacy Benefits and harms	Is the intervention clinically credible and supported by evidence or guideline consensus? Do the expected benefits outweigh the potential harms?	Supports inclusion of interventions that are clinically effective, safe and evidence-informed, and avoids ineffective or harmful minimum entitlements. Supports inclusion of interventions that provide meaningful clinical benefit while avoiding ineffective or harmful minimum benefit entitlements
Equity	Does the recommendation reduce unjustified variation in funded access? Assesses whether the recommendation improves equitable access to appropriate asthma care across different populations and healthcare settings.	The panel considered the potential effect of the recommendation on access across medical schemes, population groups and geographic settings.
Affordability Affordability and resource implications	Can the intervention be sustainably implemented within the PMB framework while Considering distributional effects, resource requirements, affordability and the potential effect on access.? Can the intervention be sustainably implemented within the PMB framework, considering resource requirements, affordability and distributional effects?	Informs funding boundaries, implementation approaches and prioritisation of high-cost interventions where appropriate. Supports definition of PMB funding boundaries and prioritisation of high-cost interventions.

EtD axis/domain	Question asked by the panel; Question considered	PMB implication
Feasibility	Are workforce, diagnostic, device and referral pathways implementable?	Supports recommendations that can be implemented within available healthcare systems, workforce capacity, diagnostic services and referral pathways.
Acceptability	Is the recommendation likely to be acceptable to patients, healthcare professionals, funders and other stakeholders? Assesses whether patients, clinicians, funders and other stakeholders are likely to support implementation of the recommendation.	Supports uptake, adherence, implementation and long-term sustainability of the recommendation
Certainty of evidence	How confident is the panel that the available evidence reflects the true effect?	Supports transparent recommendations and indicates the strength of the underlying evidence informing PMB benefit definitions
Patient values and preferences	Is there important variability in how patients value the outcomes?	Supports patient-centred recommendations and recognises the importance of shared decision-making where appropriate.
Resource use	What healthcare resources are required to implement the recommendation?	Supports efficient allocation of healthcare resources while maintaining clinically appropriate care.

Where evidence was limited, recommendations were informed by structured expert consensus using the GRADE-ADOLOPMENT process and explicit EtD deliberation.

Appendix D: Consensus Process and Voting Results

The CAC used structured independent voting and deliberative consensus meetings throughout the guideline development process. Recommendations that achieved the pre-specified consensus threshold (70%) were adopted, adapted, or excluded according to the agreed methodology. Recommendations that did not achieve the required level of agreement underwent further discussion and clarification before progressing to a second round of voting, where appropriate.

Round 2 voting focused on recommendations where clinically important disagreement remained or where clarification of PMB boundaries was required, particularly regarding allergen immunotherapy, FeNO, advanced diagnostics, physiotherapy and rehabilitation services, and biologic therapies. The Clinical Advisory Committee (CAC) used a structured, transparent consensus process throughout the development of this guideline. Recommendations derived from the evidence review and GRADE-

ADOLOPMENT process were independently assessed by committee members using predefined voting criteria. Recommendations achieving the predefined consensus threshold of **≥70% agreement** were accepted as either **Adopt**, **Adapt**, **Add/de novo**, or **Exclude**, in accordance with the agreed methodology.

Recommendations that did not achieve the required level of agreement during the initial voting round underwent structured discussion to clarify the supporting evidence, contextual considerations and PMB implications. Where consensus remained unresolved, recommendations progressed to a second round of independent voting following revision or clarification of the wording.

Round 2 deliberations focused primarily on recommendations where important clinical or policy uncertainty remained, particularly regarding allergen immunotherapy, house dust mite (HDM) sublingual immunotherapy (SLIT), FeNO, advanced diagnostic investigations, physiotherapy and rehabilitation services, and biologic therapies. These discussions sought to ensure that recommendations were evidence-informed, clinically appropriate, feasible to implement and consistent with the objectives of the PMB framework.

The final recommendations incorporated into this guideline therefore represent both the best available evidence and structured multidisciplinary consensus, while taking into account the South African healthcare context, equity considerations, affordability, implementation feasibility and the financial sustainability of medical schemes.

Consensus element	Outcome recorded in project materials
Global standards synthesised	International asthma guidelines were identified using the predefined eligibility and appraisal process, including GINA, NICE, BTS/SIGN, NAEPP and CTS
Round 1 non-consensus items Round 1 voting	Twelve recommendations did not achieve the predefined consensus threshold during the initial voting round.
After CAC discussion: Consensus deliberation	5 items were overturned/adopted, and 7 progressed to Round 2 voting. Following structured discussion and clarification, five recommendations achieved consensus and were incorporated into the guideline, while seven recommendations progressed to a second round of voting.
Round 2 outcome - Round 2 voting	Integrated elements achieved >70% consensus and were adopted into the final pathway. Recommendations achieving the predefined consensus threshold (>70% agreement) were incorporated into the final guideline and care pathways. Following revision and further deliberation, all remaining recommendations that achieved the predefined consensus threshold (≥70% agreement) were incorporated into the final guideline and care pathways.

Consensus element	Outcome recorded in project materials
Key debated boundaries Key areas of discussion	Allergen immunotherapy, HDM SLIT, biologic therapies, FeNO, bronchial challenge testing, physiotherapy and rehabilitation services.
Consensus threshold	Recommendations achieving ≥70% agreement were considered to have reached consensus.

Where consensus could not be achieved, recommendations were either excluded from the PMB guideline or deferred pending the availability of additional evidence or further policy consideration.

Appendix D2: External Review

This guideline was not subjected to a separate external peer-review process prior to finalisation. The development process nevertheless incorporated multidisciplinary expert input, structured consideration of the identified evidence and source guidelines, and review through the established guideline-development and governance processes. Future updates may incorporate formal external review as an additional quality-assurance step.

Appendix D3: Declaration and Management of Interests

All CAC and TWG members completed a standard CMS conflict-of-interest declaration prior to the first meeting. Declarations were reviewed by CMS's governance function; members with a material direct financial interest in a specific recommendation were recused from voting on that item. A summary of declarations and management actions is provided below.

Name / Role	Interest declared	Management action
Adri Kok	*none declared*	*none required*
Angelique Coetzee	*none declared*	*none required*
Brenda Morrow	*none declared*	*none required*
Cathelijn Zeijlemake	*none declared*	*none required*
Louise Wahl	*none declared*	*none required*
Mark Hyman	*none declared*	*none required*
Natheem Salie	*none declared*	*none required*
Nkateko Mathebula	*none declared*	*none required*
Nonkqubela Mxoli	*none declared*	*none required*
SimphiweRalethe	*none declared*	*none required*
ThandekaMaphumulo	*none declared*	*none required*
Tinesha Parbhoo	*none declared*	*none required*
Ameer Hohfeld	*none declared*	*none required*

Appendix E: Final Table of Recommendations

The table below presents the final set of recommendations adopted by the Clinical Advisory Committee (CAC), organised by domain (A–G), using the same column order as the current manuscript's Appendix E — ID, Domain, Clinical situation, Recommendation, Source, Consensus, PMB applicability — with two new columns inserted between Source and Consensus: Certainty of evidence and Strength of recommendation. This directly addresses RIGHT-Ad@pt Item 22 (assessment of certainty of evidence and strength of recommendation), which was previously reported only as a CAC "Consensus %", a distinct construct measuring panel agreement rather than evidence certainty.

Certainty and Strength ratings are carried over from the cited source guideline's own GRADE assessment where available (GINA 2025, NICE NG245, BTS/SIGN, NHLBI/NAEPP 2020, CTS 2021), or recorded as the CAC's explicit judgement where the source guideline did not use GRADE (marked "Not graded" / "Not GRADE-rated", with the underlying strategy or care-pathway rationale noted rather than left blank).

PMB Applicability Categories

Core PMB Care
Routine assessment, treatment, monitoring, education and follow-up services that constitute the minimum PMB standard of care for beneficiaries meeting the defined PMB criteria.

Diagnostic PMB Service
Diagnostic investigations used to establish, confirm or reassess the diagnosis of asthma within the defined PMB clinical pathway

Specialist-Directed Care
Services or interventions that require specialist assessment, referral or supervision and are provided where clinically indicated.

Advanced Therapy
Advanced Therapy comprises specialised or high-cost interventions governed by predefined clinical eligibility, specialist-oversight, response-assessment and funding criteria. Specialised or high-cost interventions requiring predefined clinical eligibility, specialist assessment, response monitoring and defined PMB funding criteria.

The recommendations below define the minimum PMB standard of care. They should be interpreted together with the relevant clinical sections of this guideline and do not preclude additional clinically appropriate investigations or interventions where justified by individual patient circumstances and the applicable provisions of the Medical Schemes Act.

This appendix is presented in two parts. Part 1 (below) is the abbreviated, publication-facing table, matching the manuscript's current Appendix E column order plus the two Item-22 additions: ID, domain, clinical situation, recommendation, source, certainty, strength, consensus, PMB applicability. Part 2 is the accompanying recommendation matrix — referenced in the guideline's own introductory text to Appendix E — giving the rationale, evidence summary, implementation considerations, and reference URL behind each recommendation (addressing RIGHT-Ad@pt Item 27, recommendation-specific rationale). The ID column is the key linking the two parts.

Part 1 — Final Table of Recommendations

ID	Domain	Clinical situation	Recommendation	Source	Certainty of evidence	Strength of recommendation	Consensus	PMB applicability
A — Prevention / Risk Reduction								
A-01	A	All people with asthma (risk reduction). Smoking exposure	Strongly advise smoking and cannabis cessation and avoidance of second-hand smoke/vaping; document exposure at every interview and offer cessation support.	GINA 2025 (Summary Guide)	Not stated	Not graded (guideline consensus)	83.3%	Core PMB Care
A-02	A	All people with asthma (environmental control). Environmental control Environmental exposure	Assess exposure to indoor allergens/irritants (e.g., dust mite, mold, pets, pests) and implement targeted mitigation when sensitization/exposure is relevant.	NHLBI/NAEPP 2020 Focused Updates	Varies by intervention (see source)	Conditional (selected topics)	83.3%	Core PMB Care

ID	Domain	Clinical situation	Recommendation	Source	Certainty of evidence	Strength of recommendation	Consensus	PMB applicability
A-03	A	All people with asthma (vaccination)	Ensure patients are up to date with locally recommended respiratory vaccines (e.g., influenza annually, COVID-19 per national policy, pneumococcal when indicated).	GINA 2025 (Summary Guide)	Not stated	Not graded (public health guidance)	83.3%	Core PMB Care
A-04	A	All people with asthma (air pollution/irritants)	Advise avoidance/minimisation of exposure to air pollution, biomass smoke and strong fumes; provide practical strategies (e.g., cooking ventilation); reduce exposure during high-pollution episodes; consider masks where appropriate.	GINA 2025 (Summary Guide)	Not stated	Not graded (guideline consensus)	83.3%	Core PMB Care
A-05	A	Occupational asthma risk or work-related symptom pattern	Ask about work-related symptom variation; if suspected, reduce exposure and refer for specialist assessment (objective testing where possible).	GINA 2025 (Summary Guide)	Not stated	Not graded	100%	Core PMB Care

ID	Domain	Clinical situation	Recommendation	Source	Certainty of evidence	Strength of recommendation	Consensus	PMB applicability
A-06	A	People with comorbidities impacting asthma control (e.g., obesity, GERD, rhinitis/sinusitis, obstructive sleep apnoea, and mental health)	Assess and manage comorbidities and psychosocial factors as part of the asthma care plan.	GINA 2025 (Summary Guide)	Not stated	Not graded	83.3%	Core PMB Care
A-07	A	History of NSAID/aspirin sensitivity or nasal polyposis	Screen for aspirin-exacerbated respiratory disease (AERD). If suspected, avoid strong COX-1 NSAIDs, use alternatives, and refer for confirmation/management if needed.	GINA 2025 (Summary Guide)	Not stated	Not graded	83.3%	Core PMB Care

ID	Domain	Clinical situation	Recommendation	Source	Certainty of evidence	Strength of recommendation	Consensus	PMB applicability
A-08	A	Education: Before initiating long-term therapy	Provide core education: what asthma is, inhaler roles, trigger recognition, and when/how to seek help; reinforce at each review.	GINA 2025 (Summary Guide)	Not stated	Not graded	83.3%	Core PMB Care
A-09	A	Physical activity and weight management (obesity and deconditioning): asthma with obesity, physical deconditioning, or exercise-related symptoms.	Encourage regular physical activity and provide weight-management support where indicated; reassure that exercise is safe when asthma is controlled, and optimise controller therapy before restricting activity.	GINA 2025 (Summary Guide)	Moderate (multiple interventional and cohort studies)	Not graded (guideline consensus / risk-reduction strategy)	83.3%	Core PMB Care

ID	Domain	Clinical situation	Recommendation	Source	Certainty of evidence	Strength of recommendation	Consensus	PMB applicability
A-10	A	Written asthma action plan: all patients with asthma, particularly those with prior exacerbations or variable control.	Provide an individualised written asthma action plan and review/update it at each visit and after any exacerbation.	GINA 2025 (Summary Guide)	High (supported by multiple trials and implementation studies)	Not graded (standard of care)	83.3%	Core PMB Care
A-11	A	Inhaler technique and adherence (preventive review): all patients at every asthma review and before any treatment escalation.	Assess inhaler technique and adherence at each visit and correct errors before changing therapy or escalating treatment.	GINA 2025 (Summary Guide)	Moderate (consistent observational and interventional evidence)	Not graded (care-pathway recommendation)	83.3%	Core PMB Care

ID	Domain	Clinical situation	Recommendation	Source	Certainty of evidence	Strength of recommendation	Consensus	PMB applicability
A-12	A	Allergen immunotherapy (selected patients): allergic asthma with clinically relevant sensitisation (e.g., dust-mite allergy) and persistent symptoms despite appropriate pharmacotherapy.	The source guidelines recommend *against* sublingual immunotherapy. However, here the CAC consider allergen immunotherapy (subcutaneous or sublingual, depending on availability) in carefully selected patients with confirmed allergic asthma and relevant exposure.	NHLBI/NAEPP 2020 Focused Updates (with supportive discussion in GINA)	Moderate	Conditional (selected patients)	**75%**	Specialist-Directed Care
B — Pharmacology (Chronic Management)								

ID	Domain	Clinical situation	Recommendation	Source	Certainty of evidence	Strength of recommendation	Consensus	PMB applicability
B-01	B	Initial treatment (newly diagnosed, ≥12 years): adolescents and adults (≥12 years) with newly diagnosed asthma or not currently receiving controller therapy.	Start anti-inflammatory reliever therapy using as-needed low-dose ICS–formoterol (AIR) as the preferred initial treatment. Do not prescribe SABA-only reliever therapy.	NICE NG245 (BTS/NICE/SIGN 2024); GINA Global Strategy for Asthma Management and Prevention (latest update); NHLBI 2020 Focused Updates	Moderate	Strong (NG245 wording: "offer") (NICE)	100%	Core PMB Care

ID	Domain	Clinical situation	Recommendation	Source	Certainty of evidence	Strength of recommendation	Consensus	PMB applicability
B-02 †	B	Not controlled on AIR (step-up to MART): asthma ≥12 years with persistent symptoms or exacerbations while using as-needed AIR therapy alone.	Escalate to low-dose MART (maintenance-and-reliever therapy) using the same ICS–formoterol inhaler for both daily maintenance and symptom relief.	NICE NG245 (BTS/NICE/SIGN 2024); GINA 2025 Strategy Report	Moderate	Strong (NICE NG245 wording: "offer")	100%	Core PMB Care

ID	Domain	Clinical situation	Recommendation	Source	Certainty of evidence	Strength of recommendation	Consensus	PMB applicability
B-03 †	B	Not controlled on low-dose MART (≥12 years): persistent symptoms and/or exacerbations despite low-dose MART and confirmed adherence/technique.	Increase to medium-dose MART with the same ICS–formoterol inhaler when persistent symptoms, frequent reliever use, night waking, activity limitation, low lung function, or recent exacerbations occur, after technique/adherence is confirmed; use symptom control, exacerbation risk and lung function together when adjusting treatment.	NICE NG245 (BTS/NICE/SIGN 2024); GINA Strategy	Moderate	Conditional ("consider") (NICE)	100%	Core PMB Care

ID	Domain	Clinical situation	Recommendation	Source	Certainty of evidence	Strength of recommendation	Consensus	PMB applicability
B-04	B	Persistent poor control on medium-dose MART: ongoing symptoms or exacerbations despite medium-dose MART.	Before further pharmacologic escalation, perform a structured reassessment: confirm diagnosis, assess adherence objectively, check inhaler technique, identify triggers/exposures, and evaluate comorbidities. If still uncontrolled, consider add-on therapy and/or specialist referral.	NICE NG245 (BTS/NICE/SIGN 2024); GINA (latest update) — "before stepping up" assessment principles	Moderate	Strong (reassessment); Conditional (add-on therapy/referral)	100%	Core PMB Care
B-05	B	Selecting an AIR/MART inhaler (≥12 years) (prescribing safety): choosing an inhaler for AIR or MART therapy.	Prescribe only an ICS–formoterol inhaler licensed for both maintenance and reliever use, and prescribe according to approved dosing instructions.	NICE NG245: Asthma: diagnosis, monitoring and chronic asthma management (2024 update)	Low to moderate (indirect/regulatory evidence)	Conditional ("consider" / safety-implementation) (NICE) — a prescribing-safety recommendation rather than a treatment-effect recommendation	100%	Core PMB Care

ID	Domain	Clinical situation	Recommendation	Source	Certainty of evidence	Strength of recommendation	Consensus	PMB applicability
B-06	B	Mild persistent asthma (alternative pathway when AIR not used): adolescents /adults ≥12 years with mild persistent asthma where anti-inflammatory reliever (AIR) therapy is not available, not tolerated, or declined.	Use either daily low-dose ICS with as-needed SABA (Option A), or intermittent ICS taken whenever SABA is used (Option B, the NHLBI/NAEPP "intermittent ICS" strategy). Patients should generally be managed within one track — AIR/MART using ICS–formoterol as reliever (Track 1), or daily ICS + SABA reliever (Track 2) — to avoid reliever confusion and duplication.	NHLBI/NAEPP 2020 Focused Updates to the Asthma Management Guidelines	Moderate	Conditional	83.3%	Core PMB Care

ID	Domain	Clinical situation	Recommendation	Source	Certainty of evidence	Strength of recommendation	Consensus	PMB applicability
B-07 †	B	Moderate–severe persistent asthma (SMART/MART preferred): persistent asthma ≥12 years requiring Step 3–4 therapy.	Use ICS-formoterol in a single inhaler as both daily controller and reliever (SMART) rather than maintenance ICS-LABA plus SABA reliever. Use ICS–formoterol in a single inhaler as both maintenance and reliever therapy (SMART/MART) in preference to maintenance ICS–LABA with SABA reliever, where clinically appropriate. Once a patient is managed within the anti-inflammatory reliever (Track 1) pathway, treatment should be escalated within that pathway (AIR → low-dose MART → medium-dose MART) rather than switching to SABA-reliever strategies. Long-acting β_2-agonists (LABAs) should never be prescribed without concomitant ICS therapy.	NHLBI/NAEPP 2020 Focused Updates to the Asthma Management Guidelines	High for ages ≥12 years (moderate for ages 4–11 years, although the recommendation applies from age 4)	Strong (NAEPP/NHLBI 2020)	100%	Core PMB Care

ID	Domain	Clinical situation	Recommendation	Source	Certainty of evidence	Strength of recommendation	Consensus	PMB applicability
B-08 †	B	Escalation within Track-1 strategy: patients on AIR or MART requiring further control (≥12 years). Long-acting β_2-agonists (LABAs) should never be prescribed without concomitant ICS therapy.	Escalate treatment within the anti-inflammatory reliever pathway (AIR → low-dose MART → medium-dose MART) rather than switching to SABA-reliever regimens; use SMART (ICS-formoterol) rather than same-dose ICS-LABA + SABA reliever. Once a patient is on AIR/MART, escalation must stay within the anti-inflammatory reliever pathway.	NHLBI/NAEPP 2020 Focused Updates to the Asthma Management Guidelines	High for ≥12 years (moderate for ages 4–11 years)	Strong	100%	Core PMB Care

ID	Domain	Clinical situation	Recommendation	Source	Certainty of evidence	Strength of recommendation	Consensus	PMB applicability
B-09	B	Uncontrolled persistent asthma on ICS-LABA (≥12 years): uncontrolled persistent asthma despite maintenance ICS-LABA with SABA reliever (traditional pathway).	Add a long-acting muscarinic antagonist (LAMA) to ICS-LABA rather than continuing the same-dose ICS-LABA alone. This applies specifically to patients already on maintenance ICS-LABA (traditional pathway) who are not using MART/AIR — LAMA is the next step only in the SABA-reliever pathway, not automatically in the MART pathway.	NHLBI/NAEPP 2020 Focused Updates to the Asthma Management Guidelines	Moderate	Conditional	100%	Core PMB Care

ID	Domain	Clinical situation	Recommendation	Source	Certainty of evidence	Strength of recommendation	Consensus	PMB applicability
B-10 †	B	Poorly controlled asthma while using PRN SABA (≥12 years); moderate–severe persistent asthma (≥4 years, key ≥12 years): asthma symptoms treated with SABA-only reliever therapy.	Moderate–severe persistent asthma (≥4y; key ≥12y)Do not continue SABA-only treatment. Start ICS-containing therapy: preferred: as-needed low-dose ICS-formoterol (AIR), or alternative: daily low-dose ICS with SABA reliever	Canadian Thoracic Society (CTS) 2021 Guideline (very mild/mild asthma); GINA Strategy 2024/2025; NHLBI/NAEPP 2020 Focused Updates	High	Strong	100%	Core PMB Care

ID	Domain	Clinical situation	Recommendation	Source	Certainty of evidence	Strength of recommendation	Consensus	PMB applicability
B-11	B	Poor adherence to daily ICS (≥12 years): poor adherence or unwillingness to take daily inhaled corticosteroid therapy.	Prefer as-needed low-dose ICS–formoterol (AIR) rather than daily ICS with SABA reliever in patients with poor adherence to daily ICS.	Canadian Thoracic Society Guideline (Very Mild/Mild Asthma); GINA Strategy 2024/2025; NAEPP/NHLBI 2020 Focused Updates	Very low	Strong	100%	Core PMB Care

ID	Domain	Clinical situation	Recommendation	Source	Certainty of evidence	Strength of recommendation	Consensus	PMB applicability
B-12 †	B	Adolescents 12–18 years, well controlled on PRN SABA but at higher risk of exacerbation: infrequent symptoms using SABA reliever only but with risk factors for severe exacerbation (e.g., prior exacerbation, over-use of SABA, allergic sensitisation, poor adherence risk).	Offer ICS-containing therapy using shared decision-making: daily low-dose ICS with SABA reliever, or as-needed low-dose budesonide/formoterol (AIR).	Canadian Thoracic Society Guideline (Very Mild/Mild Asthma)	Very low	Weak	100%	Core PMB Care

ID	Domain	Clinical situation	Recommendation	Source	Certainty of evidence	Strength of recommendation	Consensus	PMB applicability
B-13 †	B	Adolescents /adults with asthma (general principle).	Prefer an ICS-containing reliever strategy, particularly "Track 1" using as-needed low-dose ICS–formoterol as reliever-based treatment, over "Track 2" (SABA reliever).	GINA 2025 (Summary Guide)	Not GRADE-rated in GINA; based on multiple randomised and pragmatic clinical trials demonstrating reduction in severe exacerbations versus SABA-reliever strategies	Not formally GRADE-rated (strategy recommendation, GINA — preferred treatment track, not formally graded)	100%	Core PMB Care

ID	Domain	Clinical situation	Recommendation	Source	Certainty of evidence	Strength of recommendation	Consensus	PMB applicability
B-14 †	B	Step 1–2 (adolescents/adults).	Use as-needed low-dose ICS–formoterol as reliever-based treatment (Track 1).	GINA 2025 (Summary Guide)	Not GRADE-rated in GINA; the RCT evidence base behind Track 1 is robust (SYGMA-1, SYGMA-2, PRACTICAL, Novel START)	Not formally graded (GINA strategy recommendation); the underlying RCT evidence base (SYGMA-1, SYGMA-2, PRACTICAL, Novel START) is robust, but GINA does not express it using GRADE categories	100%	Core PMB Care
B-15	B	If Track 2 is used (adolescents/adults).	Avoid SABA "monotherapy behaviour" — ensure that every SABA use is accompanied by inhaled corticosteroid exposure (either concomitant ICS inhalation or a fixed-dose ICS/SABA strategy).	GINA 2025 (Summary Guide)	Not GRADE-rated in GINA	Not formally graded (GINA strategy recommendation)	100%	Core PMB Care

ID	Domain	Clinical situation	Recommendation	Source	Certainty of evidence	Strength of recommendation	Consensus	PMB applicability
B-16 †	B	Step 3 (adolescents/adults)uncontrolled asthma on Step 1–2 within the Track 1 strategy.	Initiate low-dose MART (maintenance-and-reliever therapy) using ICS–formoterol in a single inhaler as the preferred escalation within Track 1 (anchoring Step 3 to the anti-inflammatory reliever strategy).	GINA 2025 (Summary Guide)	Not GRADE-classified by GINA; based on multiple RCTs comparing ICS-formoterol reliever strategies versus fixed-dose ICS/LABA + SABA	Not formally GRADE-rated (GINA strategy recommendation)	100%	Core PMB Care
B-17 †	B	Step 4 (adolescents/adults).	Use medium-dose MART (maintenance-and-reliever therapy with ICS–formoterol) as the next escalation in Track 1 when asthma remains uncontrolled on low-dose MART.	GINA 2025 (Summary Guide)	Not GRADE-classified in GINA	Not formally GRADE-rated (GINA strategy recommendation)	100%	Core PMB Care

ID	Domain	Clinical situation	Recommendation	Source	Certainty of evidence	Strength of recommendation	Consensus	PMB applicability
B-18	B	Children 6–11 years (principle).	Ensure all children receive an ICS-containing regimen and avoid SABA-only treatment patterns.	GINA 2025 (Summary Guide)	Not formally graded; based on a consistent body of randomised-trial and observational evidence demonstrating increased exacerbation risk with SABA-only treatment	Strategy recommendation (not GRADE-rated in GINA)	100%	Core PMB Care

B-19	B	Adults/adolescents ≥12 years with mild persistent asthma (SA EML context).	Consider as-needed low-dose ICS/formoterol (anti-inflammatory reliever) as an alternative to daily low-dose ICS plus SABA reliever, depending on local STG/EML decisions, inhaler availability and patient adherence.	SA NEMLC evidence review (Nov 2025)	Moderate rather than high; downgraded because outcomes depend heavily on patient behaviour (adherence as effect modifier), differing reliever-use patterns between trials, some open-label pragmatic designs, and indirectness to some health-system contexts, though consistent exacerbation reduction	Conditional	100%	Core PMB Care

ID	Domain	Clinical situation	Recommendation	Source	Certainty of evidence	Strength of recommendation	Consensus	PMB applicability
					across studies prevents low certainty (underlying RCT base: SYGMA-1, SYGMA-2, PRACTICAL, Novel START)			
B-20	B	Persistent uncontrolled asthma despite medium/high-dose MART (≥12 years).	Reassess and correct modifiable factors (diagnosis, inhaler technique, adherence, smoking, comorbidities, environmental triggers) and confirm optimised therapy before labelling severe asthma or referring for biologic therapy.	GINA 2025 Severe Asthma Guide & Summary Guide; BTS/NICE/SIGN Guideline NG245 (2024)	Moderate	Strong (strategy recommendation — GINA)	83.3%	Core PMB Care

ID	Domain	Clinical situation	Recommendation	Source	Certainty of evidence	Strength of recommendation	Consensus	PMB applicability
B-21	B	Persistent uncontrolled asthma despite optimised medium/high-dose ICS-formoterol (MART) (≥12 years).	Add a long-acting muscarinic antagonist (LAMA) (e.g., tiotropium) to ICS-LABA therapy rather than continuing ICS-LABA alone, after a LAMA trial of at least approximately 8–12 weeks with confirmed adherence, correct inhaler technique and adequate ICS dose; continue primary care if control is achieved, or refer for specialist severe-asthma evaluation if still uncontrolled.	GINA 2025 Severe Asthma Guide; NHLBI/NAEPP 2020 Focused Updates; BTS/NICE/SIGN Guideline NG245 (2024)	Moderate	Conditional	100%	Core PMB Care

ID	Domain	Clinical situation	Recommendation	Source	Certainty of evidence	Strength of recommendation	Consensus	PMB applicability
B-22 †	B	Track-2 reliever (SABA pathway must include ICS exposure): adolescents and adults (≥12 years) managed on Track-2 therapy (SABA reliever pathway) where AIR/MART (ICS-formoterol) is unavailable, contraindicated, or declined.	Avoid SABA-only reliever use; ensure every SABA use is accompanied by inhaled corticosteroid exposure, either by taking a low-dose ICS inhalation at the same time as SABA, or by using an ICS–SABA combination reliever where available.	GINA Global Strategy for Asthma Management and Prevention (latest update)	Moderate	Conditional	100%	Core PMB Care

ID	Domain	Clinical situation	Recommendation	Source	Certainty of evidence	Strength of recommendation	Consensus	PMB applicability
B-23	B	Leukotriene receptor antagonist (LTRA) option: patients ≥12 years requiring alternative or add-on controller therapy, especially with allergic rhinitis, poor inhaler adherence, or preference against inhaled therapy.	Consider a leukotriene receptor antagonist (e.g., montelukast) as an alternative or add-on controller; prefer ICS-containing therapy for exacerbation prevention; provide counselling regarding potential neuropsychiatric adverse effects.	BTS/NICE/SIGN NG245; GINA Strategy	Moderate	Conditional	100%	Core PMB Care

ID	Domain	Clinical situation	Recommendation	Source	Certainty of evidence	Strength of recommendation	Consensus	PMB applicability
B-24	B	Allergen immunotherapy (house dust mite SLIT): allergic asthma ≥12 years with persistent symptoms despite ICS-containing therapy and confirmed clinically relevant sensitisation.	The source guidelines recommends *against* sublingual immunotherapy. However, here the CAC Consider house dust mite sublingual immunotherapy as an add-on treatment in appropriately selected patients, typically via specialist care.	GINA Strategy	Moderate	Conditional	**75%**	Specialist-Directed Care

ID	Domain	Clinical situation	Recommendation	Source	Certainty of evidence	Strength of recommendation	Consensus	PMB applicability
B-25	B	Step-down therapy: well-controlled asthma ≥12 years on stable ICS-containing treatment with low exacerbation risk.	Step down treatment after sustained control (approximately 2–3 months) to the lowest effective ICS dose, reducing the dose gradually (approximately 25–50%); do not completely stop ICS therapy unless under supervised diagnostic review.	GINA Strategy	Moderate	Strong	100%	Core PMB Care

ID	Domain	Clinical situation	Recommendation	Source	Certainty of evidence	Strength of recommendation	Consensus	PMB applicability
B-26	B	Severe asthma add-on options (specialist-linked): persistent uncontrolled asthma ≥12 years despite optimised high-level therapy and LAMA, after specialist assessment.	In specialist care, consider additional Step-5 add-ons such as add-on low-dose azithromycin (adults) following safety screening, or bronchial thermoplasty in selected adults where appropriate.	GINA Severe Asthma Guide	Moderate (azithromycin); Low–Moderate (thermoplasty)	Conditional	83.3%	Specialist-Directed Care

ID	Domain	Clinical situation	Recommendation	Source	Certainty of evidence	Strength of recommendation	Consensus	PMB applicability
B-27	B	Non-recommended chronic asthma treatments (safety statement): chronic asthma management ≥12 years — prevention of unsafe prescribing.	Avoid SABA-only chronic therapy, routine oral beta-agonists, and routine oral theophylline for control; maintenance oral corticosteroids should be used only as a last resort under specialist care.	GINA Strategy	Moderate	Strong	100%	Core PMB Care
C — Diagnosis								

ID	Domain	Clinical situation	Recommendation	Source	Certainty of evidence	Strength of recommendation	Consensus	PMB applicability
C-01	C	Suspected asthma (all ages): patients with symptoms suggestive of asthma.	Confirm the diagnosis and document objective evidence of variable expiratory airflow limitation where feasible. Diagnosis requires BOTH (a) a history of variable respiratory symptoms AND (b) objective evidence of variable airflow limitation (current or historical) via spirometry with bronchodilator reversibility, serial PEF variability, or bronchial challenge.	GINA 2025 (Summary Guide); NICE NG245: Asthma diagnosis, monitoring and chronic asthma management	Moderate	Strong	83.3%	Diagnostic PMB Service

ID	Domain	Clinical situation	Recommendation	Source	Certainty of evidence	Strength of recommendation	Consensus	PMB applicability
C-02	C	Adults with a history suggestive of asthma: initial assessment in primary care.	Measure FeNO and/or blood eosinophils as an initial adjunct test to support the probability of Type-2 airway inflammation; diagnose asthma if eosinophils are above the lab reference range or FeNO ≥50 ppb. No single test alone confirms asthma — diagnosis requires a compatible clinical history plus objective evidence of variable airflow limitation. Whenever feasible, confirm asthma with objective evidence of variable expiratory airflow limitation (e.g., spirometry with bronchodilator reversibility or PEF variability).	NG245 (BTS/NICE/SIGN 2024)	Moderate	Conditional	**87.5%**	Specialist-Directed Care

ID	Domain	Clinical situation	Recommendation	Source	Certainty of evidence	Strength of recommendation	Consensus	PMB applicability
C-03	C	Adults/young people with persistent diagnostic uncertainty: adults or children ≥5 years with suspected asthma in whom diagnosis remains uncertain after initial clinical assessment or biomarker testing.	Perform spirometry with bronchodilator reversibility testing to demonstrate variable expiratory airflow limitation. Asthma is supported when FEV1 increases by ≥12% and ≥200 mL after bronchodilator (or ≥10% of predicted FEV1 in children/young people, per NG245).	NG245 (BTS/NICE/SIGN 2024); GINA Global Strategy for Asthma Management and Prevention (latest update)	Moderate	Strong	83.3%	Diagnostic PMB Service

ID	Domain	Clinical situation	Recommendation	Source	Certainty of evidence	Strength of recommendation	Consensus	PMB applicability
C-04	C	Spirometry not available or delayed (adults and children ≥5 years): patients with suspected asthma in settings where spirometry is unavailable, delayed, or cannot be performed.	Measure peak expiratory flow (PEF) twice daily for 2 weeks using a validated peak flow meter and symptom diary; diagnose asthma if PEF variability (amplitude % mean) is ≥20%. PEF monitoring should be followed by spirometry confirmation when access becomes available.	NG245 (BTS/NICE/SIGN 2024); GINA Global Strategy for Asthma Management and Prevention (latest update)	Moderate	Conditional (useful only when spirometry is unavailable)	83.3%	Diagnostic PMB Service

ID	Domain	Clinical situation	Recommendation	Source	Certainty of evidence	Strength of recommendation	Consensus	PMB applicability
C-05	C	Asthma suspected but not confirmed by initial tests: patients with suspected asthma in whom diagnosis remains uncertain after spirometry, FeNO/eosinophils and/or PEF monitoring.	Refer for bronchial challenge testing (bronchial provocation testing) or specialist respiratory assessment; diagnose asthma if bronchial hyperresponsiveness is demonstrated. FeNO can help identify steroid-responsive Type-2 inflammation in children, but it is not specific for asthma and must be interpreted alongside clinical features and lung function.	NG245 (BTS/NICE/SIGN 2024); GINA Global Strategy for Asthma Management and Prevention (latest update)	Moderate	Conditional	**87.5%**	Specialist-Directed Care

ID	Domain	Clinical situation	Recommendation	Source	Certainty of evidence	Strength of recommendation	Consensus	PMB applicability
C-06	C	Children 5–16 years with a history suggestive of asthma presenting with symptoms suggestive of asthma.	Measure FeNO as the initial objective test; diagnose asthma if FeNO ≥35 ppb. If FeNO is not elevated or unavailable, perform spirometry with bronchodilator reversibility; if spirometry cannot be performed, consider PEF monitoring. Diagnosis should be based on compatible clinical history together with objective evidence of variable airflow limitation.	NG245 (BTS/NICE/SIGN 2024); GINA Global Strategy for Asthma Management and Prevention (latest update)	Moderate	Conditional	100%	Diagnostic PMB Service

ID	Domain	Clinical situation	Recommendation	Source	Certainty of evidence	Strength of recommendation	Consensus	PMB applicability
C-07	C	Children under 5 years with suspected asthma presenting with recurrent wheeze or symptoms suggestive of asthma.	Do not attempt a definitive diagnosis based on objective testing, as reliable lung function testing is usually not feasible in this age group. Offer a time-limited trial of inhaled corticosteroid (ICS) therapy with regular clinical review (typically 6–8 weeks); continue treatment if clear improvement is observed and reassess periodically. If symptoms persist or diagnostic uncertainty remains, attempt objective testing (spirometry/FeNO) once the child reaches approximately 5 years of age, or refer for specialist assessment. Improvement during treatment and recurrence after stopping supports a probable asthma phenotype.	NG245 (BTS/NICE/SIGN 2024); GINA Global Strategy for Asthma Management and Prevention (latest update)	Low–Moderate	Conditional	83.3%	Diagnostic PMB Service

ID	Domain	Clinical situation	Recommendation	Source	Certainty of evidence	Strength of recommendation	Consensus	PMB applicability
C-08	C	Pregnancy with suspected asthma where diagnosis is not confirmed: pregnant patients with suspected asthma in whom diagnostic confirmation has not yet been achieved.	Continue or start ICS-containing treatment if clinically indicated and monitor control closely during pregnancy; do not stop or reduce inhaled corticosteroids inappropriately, and do not delay treatment for symptomatic patients. Defer bronchial provocation testing until after delivery unless specialist respiratory assessment determines it is essential.	GINA 2025 (Summary Guide); GINA Strategy (latest update)	Moderate	Strong	83.3%	Diagnostic PMB Service

ID	Domain	Clinical situation	Recommendation	Source	Certainty of evidence	Strength of recommendation	Consensus	PMB applicability
C-09	C	Suspected asthma in patients already using ICS or controller therapy.	Do not exclude asthma solely on the basis of normal spirometry while on treatment. Attempt objective confirmation by repeating spirometry during symptoms, serial PEF monitoring, or reviewing historical lung function records. If safe, consider a supervised step-down of ICS to permit diagnostic testing.	GINA Strategy; NICE NG245	Moderate	Conditional	83.3%	Diagnostic PMB Service
C-10	C	Diagnostic confirmation after acute exacerbation or emergency visit.	After an acute asthma-like episode, arrange objective testing (spirometry ± PEF monitoring) once clinically stable, typically 4–6 weeks post-exacerbation.	GINA Strategy	Moderate	Strong	83.3%	Diagnostic PMB Service
C-11	C	Suspected occupational asthma.	Assess for a work-related symptom pattern. If suspected, perform serial PEF measurements at and away from work and refer early for specialist evaluation.	GINA Strategy; BTS Occupational Asthma guidance	Moderate	Strong	83.3%	Diagnostic PMB Service

ID	Domain	Clinical situation	Recommendation	Source	Certainty of evidence	Strength of recommendation	Consensus	PMB applicability
C-12	C	Older adults, smokers, or patients with chronic airflow limitation (possible COPD or asthma-COPD overlap).	In patients with persistent post-bronchodilator obstruction, assess for asthma-COPD overlap using history, variability, and response to ICS, rather than excluding asthma.	GINA Strategy	Moderate	Conditional	83.3%	Diagnostic PMB Service
C-13	C	Suspected dysfunctional breathing or inducible laryngeal obstruction (VCD/ILO).	Consider alternative diagnoses when symptoms are disproportionate to lung function. Refer for respiratory physiotherapy and/or ENT assessment if suspected.	GINA Strategy	Low–Moderate	Conditional	83.3%	Diagnostic PMB Service

ID	Domain	Clinical situation	Recommendation	Source	Certainty of evidence	Strength of recommendation	Consensus	PMB applicability
C-14 †	C	Other acceptable objective evidence of asthma variability.	Accept documented variability over time as objective evidence, including improvement after a 4-week ICS trial, prior spirometry variability, or exercise challenge testing where available.	GINA Strategy	Moderate	Conditional	83.3%	Diagnostic PMB Service
C-15	C	Minimum documentation requirements for confirmed asthma.	Document diagnostic evidence in the medical record, including symptom pattern, objective test results (values and date), treatment at the time of testing, risk factors, and exacerbation history.	GINA Strategy; NICE NG245	Moderate	Strong	83.3%	Diagnostic PMB Service
D — Monitoring / Follow-up								

ID	Domain	Clinical situation	Recommendation	Source	Certainty of evidence	Strength of recommendation	Consensus	PMB applicability
D-01	D	All people with asthma during routine follow-up visits.	At every follow-up visit, perform a structured asthma review documenting both (1) current symptom control — daytime symptoms, night waking, activity limitation, reliever use — and (2) future risk of adverse outcomes, including exacerbations in the past 12 months (oral steroid courses, ED visits, hospitalisation), prior ICU admission or intubation, reliever overuse, lung function (FEV1 or PEF), adherence and inhaler technique, smoking/vaping exposure, and comorbidities. Identify and address modifiable risk factors and adjust treatment accordingly.	GINA 2025 (Summary Guide); GINA Global Strategy for Asthma Management and Prevention (latest update); NICE NG245 asthma monitoring recommendations	Moderate	Strong	83.3%	Monitoring PMB Service

ID	Domain	Clinical situation	Recommendation	Source	Certainty of evidence	Strength of recommendation	Consensus	PMB applicability
D-02	D	All people with asthma undergoing risk assessment.	At every asthma review, document both current symptom control (daytime symptoms, night waking, activity limitation, reliever use) and future risk factors for exacerbations and adverse outcomes, including exacerbation history in the last 12 months (especially ED visits/hospitalisation), ICU admission or intubation history, reliever overuse, lung function (FEV1/PEF where available), comorbidities, ongoing exposures (smoking/vaping, biomass, occupational triggers, allergens), adherence and inhaler technique, and medication access/affordability barriers. Modifiable risks should be actively addressed with a documented action plan.	GINA 2025 (Summary Guide); GINA Global Strategy for Asthma Management and Prevention (latest update); BTS/SIGN/NICE NG245 asthma guideline	Moderate	Strong	83.3%	Monitoring PMB Service

ID	Domain	Clinical situation	Recommendation	Source	Certainty of evidence	Strength of recommendation	Consensus	PMB applicability
D-03	D	Patients with confirmed asthma receiving ongoing controller therapy, including those newly started on inhaled corticosteroid (ICS) treatment.	Measure lung function before starting ICS (when possible), again after 3–6 months, then at least every 1–2 years, monitoring more often in high-risk patients (e.g., prior severe exacerbation, poor control, persistent symptoms, low baseline lung function, smokers, or suspected occupational exposure). Spirometry is preferred; where unavailable, serial peak expiratory flow (PEF) monitoring with symptom tracking may be used, with appropriate quality control.	GINA 2025 (Summary Guide); GINA Strategy Report – latest edition	Moderate	Strong	100%	Monitoring PMB Service

ID	Domain	Clinical situation	Recommendation	Source	Certainty of evidence	Strength of recommendation	Consensus	PMB applicability
D-04	D	Self-management support for patients with confirmed or suspected asthma.	Provide a written asthma action plan and ensure the patient/caregiver understands how to recognise worsening asthma, step up treatment, and seek care. The plan should include daily controller therapy, reliever use instructions, step-up treatment during deterioration, indications for urgent care, and emergency contact details. Use locally approved templates and review the plan at follow-up visits.	GINA 2025 (Summary Guide); GINA Strategy Report / Summary Guide (latest update)	Moderate (approaching high)	Strong	83.3%	Monitoring PMB Service

ID	Domain	Clinical situation	Recommendation	Source	Certainty of evidence	Strength of recommendation	Consensus	PMB applicability
D-05 †	D	Patients prescribed inhaled asthma therapy.	Train inhaler technique at initiation and re-check regularly, including after device changes; correct errors with demonstration and teach-back. Technique should be checked at initiation, at each routine review, after an exacerbation, after a device change, when control deteriorates, and before stepping up treatment. Where possible, select an inhaler device the patient can use correctly after instruction; a spacer is recommended with pressurised metered-dose inhalers, particularly in children and older adults. Document technique education and reassessment in the clinical record.	GINA 2025 (Summary Guide); GINA Strategy (latest update)	Moderate	Strong	83.3%	Monitoring PMB Service

ID	Domain	Clinical situation	Recommendation	Source	Certainty of evidence	Strength of recommendation	Consensus	PMB applicability
D-06	D	Patients with uncontrolled asthma or prior to escalation of maintenance therapy.	Before stepping up pharmacologic therapy, reassess modifiable causes of poor control: confirmation of the diagnosis with objective evidence where possible, medication adherence (including refill review where available), observed inhaler technique using teach-back, reliever overuse and controller underuse, environmental and occupational exposures (e.g., smoking, allergens), and comorbid conditions (e.g., allergic rhinitis, obesity, GERD, OSA, psychological factors). Treatment escalation should only occur after these factors have been addressed where possible.	GINA 2025 (Summary Guide); GINA Strategy Report (section 'Difficult-to-treat and severe asthma'); BTS/NICE NG245 step-up guidance	Moderate	Strong	83.3%	Monitoring PMB Service

ID	Domain	Clinical situation	Recommendation	Source	Certainty of evidence	Strength of recommendation	Consensus	PMB applicability
D-07	D	Patients with well-controlled asthma on maintenance therapy, including those on maintenance ICS-containing therapy with SABA reliever, or anti-inflammatory reliever therapy (AIR/MART using ICS-formoterol).	Consider step-down after good control has been maintained for 2–3 months, provided there are no recent exacerbations and risk factors are addressed; reduce gradually with close monitoring and avoid abrupt cessation of ICS. Step-down is dose reduction, not removal of anti-inflammatory protection. For maintenance ICS + SABA regimens, gradually reduce the maintenance ICS dose while maintaining some controller therapy where possible. For AIR/MART regimens, reduce maintenance dosing first; reliever-only ICS-formoterol may be appropriate in selected well-controlled patients; do not switch to SABA-only therapy.	GINA 2025 (Summary Guide); GINA Global Strategy for Asthma Management and Prevention; BTS/SIGN/NICE NG245 step-down recommendations	Moderate	Strong	83.3%	Monitoring PMB Service

ID	Domain	Clinical situation	Recommendation	Source	Certainty of evidence	Strength of recommendation	Consensus	PMB applicability
D-08	D	Patients ≥5 years with suspected asthma in whom diagnostic uncertainty persists after initial objective testing, or with established asthma in whom treatment adjustment (initiation, escalation, or step-down of ICS-containing therapy) is being considered.	Consider fractional exhaled nitric oxide (FeNO) as an adjunct to standard objective testing (spirometry ± bronchodilator reversibility or PEF monitoring) to support diagnosis of Type-2 (eosinophilic) airway inflammation and to guide initiation, adjustment, or step-down of ICS-containing therapy in appropriate clinical contexts. FeNO should not be used as a standalone diagnostic test and must be interpreted together with clinical assessment and lung function testing.	NHLBI/NAEPP 2020 Focused Updates; GINA 2025 (Global Strategy for Asthma Management and Prevention); NICE NG245	Moderate	Conditional (weak)	100%	Monitoring PMB Service

ID	Domain	Clinical situation	Recommendation	Source	Certainty of evidence	Strength of recommendation	Consensus	PMB applicability
D-09	D	Patients with high SABA use / reliever overuse.	Monitor reliever inhaler use at each visit. Use of ≥3 SABA canisters/year (or frequent reliever use on >2 days/week) should trigger treatment review and controller optimisation.	GINA 2025	High	Strong	83.3%	Monitoring PMB Service
D-10	D	Adherence monitoring in patients with asthma.	Assess adherence to controller therapy at every visit using open questioning, pharmacy refill review, or dose counters.	GINA 2025	Moderate	Strong	83.3%	Monitoring PMB Service
D-11	D	Exacerbation follow-up.	Review patients within 2–7 days after an exacerbation or emergency visit and reassess control, triggers, and the treatment plan.	GINA 2025	Moderate	Strong	83.3%	Monitoring PMB Service
D-12	D	Comorbidity screening in patients with asthma.	Screen periodically for comorbidities affecting control: allergic rhinitis, obesity, GERD, anxiety/depression, sleep apnoea, and smoking/vaping exposure.	GINA 2025	Moderate	Strong	83.3%	Monitoring PMB Service

ID	Domain	Clinical situation	Recommendation	Source	Certainty of evidence	Strength of recommendation	Consensus	PMB applicability
D-13	D	Environmental and occupational exposure review.	Assess exposure to tobacco smoke, indoor allergens, air pollution, and occupational triggers at follow-up visits.	GINA 2025	Moderate	Strong	83.3%	Monitoring PMB Service
D-14	D	Vaccination review in patients with asthma.	Recommend annual influenza vaccination and ensure routine immunisations are up to date.	GINA 2025	Moderate	Strong	83.3%	Monitoring PMB Service
D-15	D	Assessment of psychosocial risk factors.	Assess mental health, health literacy, and social barriers affecting self-management.	GINA 2025	Low–Moderate	Conditional	100%	Monitoring PMB Service

ID	Domain	Clinical situation	Recommendation	Source	Certainty of evidence	Strength of recommendation	Consensus	PMB applicability
D-16	D	Patients with persistent respiratory symptoms despite good asthma control (possible role for physical activity and rehabilitation).	Encourage regular physical activity and consider referral for breathing retraining/physiotherapy in patients with dysfunctional breathing, exercise limitation, or persistent dyspnoea despite good control.	GINA 2025	Moderate	Conditional	**87.5%**	Monitoring PMB Service
D-17	D	Identification of high-risk asthma.	Flag patients with prior ICU admission, ≥2 steroid bursts/year, low FEV1, or poor adherence for specialist review.	GINA 2025	Moderate–High	Strong	83.3%	Monitoring PMB Service
E — Exacerbations (Acute Asthma)								

ID	Domain	Clinical situation	Recommendation	Source	Certainty of evidence	Strength of recommendation	Consensus	PMB applicability
E-01	E	Acute asthma exacerbation (initial assessment).	Assess severity while starting reliever therapy and oxygen (if needed): check for anaphylaxis; assess dyspnoea, respiratory rate, pulse, SpO2, and lung function (e.g., PEF).	GINA 2025 (Summary Guide)	Not stated	Strategy recommendation	100%	Acute PMB/Emergency Care
E-02	E	Acute breathlessness where asthma exacerbation is suspected.	Consider alternative or coexisting diagnoses (e.g., heart failure, upper airway dysfunction, foreign body, pulmonary embolism) if presentation is atypical or response is poor.	GINA 2025 (Summary Guide)	Not stated	Not graded	83.3%	Acute PMB/Emergency Care
E-03	E	Investigations during acute exacerbation.	Do not routinely perform chest X-ray or arterial blood gases and do not routinely prescribe antibiotics; reserve these for complications or atypical features.	GINA 2025 (Summary Guide)	Not stated	Not graded	100%	Acute PMB/Emergency Care
E-04	E	Sedation in acute asthma.	Do not use sedatives in acute asthma exacerbations.	GINA 2025 (Summary Guide)	Not stated	Not graded	100%	Acute PMB/Emergency Care

ID	Domain	Clinical situation	Recommendation	Source	Certainty of evidence	Strength of recommendation	Consensus	PMB applicability
E-05	E	Monitoring response during acute exacerbation.	Monitor symptoms and SpO2 frequently; reassess lung function after approximately 1 hour and titrate therapy; transfer/escalate to higher-level care if worsening or if response is inadequate.	GINA 2025 (Summary Guide)	Not stated	Strategy recommendation	100%	Acute PMB/Emergency Care
E-06	E	Post-exacerbation / discharge planning.	Before discharge, optimise ICS-containing maintenance therapy, provide/refresh an action plan, review inhaler technique, and arrange early follow-up.	GINA 2025 (Summary Guide)	Not stated	Strategy recommendation	100%	Acute PMB/Emergency Care

E-07	E	All people with asthma at routine follow-up visits, including patients with apparently 'good symptom control'.	At every asthma review, assess future exacerbation risk separately from current symptom control, and document key risk factors and address modifiable risks. Minimum risk review should include: at least 1 exacerbation requiring oral corticosteroids, an ED visit, or hospitalisation in the past 12 months; prior ICU admission or intubation for asthma (high-risk marker); reliever overuse; low lung function (FEV1/PEF where available); poor adherence and/or incorrect inhaler technique; ongoing exposures (smoking/vaping, biomass, occupational/allergen triggers); and comorbidities that worsen asthma outcomes (e.g., allergic rhinitis/sinusitis, obesity, GERD, OSA, anxiety/depression). Frequent SABA use should trigger review of adherence, technique, and controller therapy; where dispensing data are available, 3 or more SABA	GINA (latest update); BTS/NICE/SIGN NG245 (structured review and risk assessment approach); SABINA programme evidence supporting SABA overuse risk thresholds	Not stated	Not graded / strategy statement (GINA)	83.3%	Acute PMB/Emergency Care

ID	Domain	Clinical situation	Recommendation	Source	Certainty of evidence	Strength of recommendation	Consensus	PMB applicability
			canisters/year indicates increased exacerbation risk and should prompt treatment review.					
E-08	E	Acute exacerbation with signs of severe exacerbation / needs urgent transfer.	Arrange immediate transfer to an acute care facility if there are signs of severe exacerbation.	GINA 2025 (Summary Guide)	Not stated	Not graded (GINA)	100%	Acute PMB/Emergency Care
E-09	E	Severe acute exacerbation (initial ED management).	Immediately give inhaled SABA plus inhaled ipratropium plus oxygen plus systemic corticosteroids; transfer to ICU if drowsy, confused, or if silent chest is present.	GINA 2025 (Summary Guide)	Not stated	Not graded (GINA)	100%	Acute PMB/Emergency Care

ID	Domain	Clinical situation	Recommendation	Source	Certainty of evidence	Strength of recommendation	Consensus	PMB applicability
E-10	E	Moderate-severe exacerbation needing systemic corticosteroids.	Start oral corticosteroids (except in mild exacerbations): adults, prednisolone 40-50 mg daily for 5-7 days; children dosed as per guide.	GINA 2025 (Summary Guide)	Not stated	Not graded (GINA)	83.3%	Acute PMB/Emergency Care
E-11	E	Severe exacerbation with inadequate response to intensive initial treatment (acute care facility).	Consider IV magnesium sulfate if there is inadequate response to intensive initial treatment.	GINA 2025 (Summary Guide)	Not stated	Not graded (GINA)	100%	Acute PMB/Emergency Care
E-12	E	Oxygen therapy during acute exacerbation.	Titrate oxygen to maintain an SpO2 target of 93-95% in adults/adolescents (>=94% in children 6-12 years), adjusted for altitude where appropriate.	GINA 2025 (Summary Guide)	Not stated	Not graded (GINA)	100%	Acute PMB/Emergency Care

E-13	E	Post-treatment reassessment after acute asthma exacerbation (after initial bronchodilator plus systemic corticosteroid therapy and an observation period).	Determine disposition (discharge vs ward admission vs ICU transfer) based on clinical response, lung function, and risk factors. Discharge may be considered only if ALL of the following are present: symptoms substantially improved; no severe dyspnoea or fatigue; SpO2 >=94% on room air; PEF or FEV1 >=60-80% predicted or personal best (where available); reliever needed no more often than every 3-4 hours; reliable access to medication and follow-up. Hospital admission is indicated if: incomplete response after initial treatment; persistent hypoxaemia; PEF/FEV1 <60% predicted/personal best; need for repeated bronchodilators; or significant risk factors for poor outcome. ICU/urgent escalation is indicated if any of: silent chest; drowsiness, confusion, exhaustion; rising or high PaCO2; worsening	GINA 2025 (Summary Guide - acute asthma management)	Not formally graded in GINA	Strategy recommendation (care-pathway safety recommendation; not GRADE-rated in GINA)	100%	Acute PMB/Emergency Care

ID	Domain	Clinical situation	Recommendation	Source	Certainty of evidence	Strength of recommendation	Consensus	PMB applicability
			hypoxaemia despite oxygen; or impending respiratory arrest.					

E-14	E	Post-exacerbation review / high-risk follow-up package. After any severe exacerbation (requiring systemic corticosteroids and/or ED visit/hospital admission/ICU), or 'frequent exacerbator' phenotype (>=2 severe exacerbations in 12 months and/or >=1 hospital/ICU admission in 12 months), including	Conduct an early structured post-exacerbation review (preferably within 2-7 days, and again within 4-6 weeks) to: confirm diagnosis; step up/optimise ICS-containing controller therapy; review and correct inhaler technique; verify adherence; identify and address triggers/exposures and comorbidities; provide/refresh a written asthma action plan; and document exacerbation history as a high-risk marker requiring closer follow-up and/or specialist referral.	GINA 2025 (Summary Guide)	Not stated (not GRADE-rated in GINA)	Strategy / care-pathway recommendation (not GRADE-rated in GINA)	83.3%	Acute PMB/Emergency Care

ID	Domain	Clinical situation	Recommendation	Source	Certainty of evidence	Strength of recommendation	Consensus	PMB applicability
		patients with apparently 'good symptom control'.						
F — Specialist Therapies / Severe Asthma								

ID	Domain	Clinical situation	Recommendation	Source	Certainty of evidence	Strength of recommendation	Consensus	PMB applicability
F-01 †	F	Step 5 (adolescents/adults): patient uncontrolled on optimized Step 4 therapy (e.g., medium/high-dose ICS-LABA +/- MART) with persistent symptoms and/or exacerbations.	Refer for specialist evaluation to confirm diagnosis, assess inhaler technique and adherence, identify modifiable risk factors and comorbidities, and perform phenotype assessment before initiating add-on therapy (e.g., LAMA or biologics).	GINA 2025 (Summary Guide); GINA Severe Asthma Guide 2025	Not GRADE-rated in GINA	Not GRADE-rated (strategy/care-pathway recommendation)	83.3%	Specialist-Directed Care

ID	Domain	Clinical situation	Recommendation	Source	Certainty of evidence	Strength of recommendation	Consensus	PMB applicability
F-02	F	Difficult-to-treat or severe asthma (Step 4-5 or frequent exacerbations): patient uncontrolled despite optimized medium/high-dose ICS-containing therapy, or >=2 OCS courses/year, or hospitalization/ICU.	Refer for specialist evaluation to confirm diagnosis, assess adherence/technique, and perform phenotyping (e.g., Type 2 markers) to guide add-on therapy. Refer for specialist severe-asthma assessment before escalation to long-term OCS or biologics. Specialist evaluation should: confirm the asthma diagnosis; assess adherence and inhaler technique; identify and manage modifiable factors (exposures, smoking, occupational triggers); evaluate and treat comorbidities; perform inflammatory phenotyping (e.g., Type-2 biomarkers); and determine eligibility for add-on therapy (LAMA, biologics).	GINA 2025 (Summary Guide - Severe asthma / Step 5 management)	Not GRADE-rated in GINA (GINA does not apply GRADE to system-level pathway recommendations)	Not graded (strategy/care-pathway recommendation)	83.3%	Specialist-Directed Care

ID	Domain	Clinical situation	Recommendation	Source	Certainty of evidence	Strength of recommendation	Consensus	PMB applicability
F-03	F	Severe asthma (adolescents/adults) uncontrolled despite optimized high-dose ICS-LABA (or MART where used) with evidence of Type 2 inflammation, after adherence/technique/exposures/comorbidities optimized.	Consider add-on biologic therapy (e.g., anti-IgE, anti-IL5/IL5R, anti-IL4R) according to phenotype and eligibility criteria, and refer to a specialist severe-asthma service for structured assessment and phenotype-directed add-on therapy. In eligible patients with confirmed Type-2 inflammation, initiate targeted biologic therapy (anti-IgE, anti-IL-5/IL-5R, or anti-IL-4R-alpha) according to phenotype and predefined eligibility criteria.	GINA 2025 (Summary Guide)	Not stated (supported by multiple RCTs in phenotype-selected populations; not formally GRADE-rated in GINA)	Strong (care-pathway recommendation, not formally GRADE-labelled but operationally mandatory within the stepwise treatment algorithm)	**75%**	Advanced Therapy

ID	Domain	Clinical situation	Recommendation	Source	Certainty of evidence	Strength of recommendation	Consensus	PMB applicability
F-04	F	Persistent uncontrolled asthma on ICS-LABA (Step 4/5) despite optimization, where LAMA is appropriate (add-on, often before/alongside the biologic pathway depending on phenotype and access).	Consider add-on LAMA as part of specialist-supported step-up where indicated and available (may be via a separate inhaler or a triple therapy inhaler).	NHLBI/NAEPP 2020 Focused Updates; GINA 2025 (Summary Guide); GINA Severe Asthma Guide 2025	Moderate (NAEPP); not GRADE-rated in GINA	Conditional (GINA lists LAMA as an add-on option within severe asthma pathways, not GRADE-labelled; NAEPP grades this as conditional in patients >=12 years)	100%	Specialist-Directed Care

ID	Domain	Clinical situation	Recommendation	Source	Certainty of evidence	Strength of recommendation	Consensus	PMB applicability
F-05	F	Consideration of bronchial thermoplasty or other advanced interventions: selected adults with severe asthma after optimization and specialist assessment, generally after failure/ineligibility of other add-ons.	Only consider advanced interventions in specialist centres after optimisation of standard therapy and assessment of eligibility and risks. Consider bronchial thermoplasty (with registry enrollment) only in specialist centers and only for carefully selected patients.	GINA 2025 (Summary Guide); NAEPP/NHLBI 2020 Focused Updates	Low (NAEPP, for bronchial thermoplasty comparisons, using NHLBI as anchor); GINA also flags limited evidence and the need for careful selection	Conditional recommendation against bronchial thermoplasty compared with standard care (NAEPP/NHLBI 2020)	83.3%	Advanced Therapy

ID	Domain	Clinical situation	Recommendation	Source	Certainty of evidence	Strength of recommendation	Consensus	PMB applicability
F-06	F	Suspected severe asthma: need to distinguish uncontrolled vs difficult-to-treat vs severe asthma before add-ons.	Apply a structured classification and only label 'severe asthma' after: diagnosis confirmed, adherence and inhaler technique verified, exposures addressed, comorbidities treated, and the patient remains uncontrolled on optimized high-dose ICS-LABA (+/- MART as applicable).	GINA Severe Asthma Guide 2025	Not GRADE-rated in GINA	Not graded (GINA care-pathway definition/strategy)	83.3%	Specialist-Directed Care
F-07	F	Step-5 assessment: objective documentation required for escalation approval (biologics/OCS/LAMA).	Use a Step-5 minimum dataset (mandatory documentation package) before any high-cost/high-risk add-on is approved.	GINA Severe Asthma Guide 2025	Not GRADE-rated in GINA	Not graded (implementation requirement)	83.3%	Specialist-Directed Care

ID	Domain	Clinical situation	Recommendation	Source	Certainty of evidence	Strength of recommendation	Consensus	PMB applicability
F-08	F	Severe asthma with Type 2 inflammation: biologic eligibility and selection.	Specify a local biologic eligibility framework (phenotype -> criteria -> agent class -> monitoring), including pre-biologic optimization requirements and biomarker cut-offs adopted locally.	GINA Severe Asthma Guide 2025	Not GRADE-rated in GINA	Not graded (GINA strategy; eligibility framework is a local operationalization)	**75%**	Advanced Therapy
F-09 †	F	After initiating a biologic (or add-on LAMA): need to assess response and decide on continuation.	Implement a formal response review at approximately 3-6 months (and at least annually) with predefined continuation/stopping rules.	GINA Severe Asthma Guide 2025	Not GRADE-rated in GINA	Not graded (care-pathway/implementation)	83.3%	Advanced Therapy

ID	Domain	Clinical situation	Recommendation	Source	Certainty of evidence	Strength of recommendation	Consensus	PMB applicability
F-10	F	Chronic oral corticosteroid (OCS) exposure risk in difficult-to-treat/severe asthma.	Adopt an OCS stewardship approach: minimize maintenance OCS, document cumulative exposure, actively manage OCS adverse effects, and prioritize steroid-sparing add-ons when eligible.	GINA Severe Asthma Guide 2025	Not GRADE-rated in GINA	Not graded (strategy/implementation)	83.3%	Advanced Therapy

F-11	F	Add-on macrolide (e.g., azithromycin) in selected adults: adult severe asthma with persistent symptoms/exacerbations despite optimisation, where Type 2-targeted biologics are not indicated/available or exacerbations persist despite other add-ons; specialist setting.	Consider a trial of add-on low-dose azithromycin in carefully selected adults, with safety screening and monitoring (QT risk, hearing, resistance considerations).	GINA Severe Asthma Guide 2025	Not GRADE-rated in GINA	Not graded (GINA strategy recommendation)	100%	Specialist-Directed Care

ID	Domain	Clinical situation	Recommendation	Source	Certainty of evidence	Strength of recommendation	Consensus	PMB applicability
F-12	F	Biologic 'trial, assess response, stop/switch' rules: severe asthma eligible for biologic therapy (Type 2 markers and exacerbation burden documented), starting Step-5 biologic.	Start biologic only after optimisation; define a formal assessment window (e.g., approximately 3-6 months) and response criteria; stop or switch if response is inadequate; continue to minimise OCS and reassess phenotype if therapy fails.	GINA Severe Asthma Guide 2025	Not GRADE-rated in GINA	Not graded (GINA care-pathway recommendation)	83.3%	Advanced Therapy
G — Non-Pharmacologic (Foundational) Asthma Management								
G-01	G	All patients with asthma.	Provide structured asthma education and a personalised written asthma action plan.	GINA Strategy; BTS/NICE/SIGN NG245	High	Strong	83.3%	Core PMB Care

ID	Domain	Clinical situation	Recommendation	Source	Certainty of evidence	Strength of recommendation	Consensus	PMB applicability
G-02	G	All patients prescribed inhaled therapy.	Assess and teach inhaler technique at initiation and at every follow-up.	GINA Strategy; NICE NG245	High	Strong	83.3%	Core PMB Care
G-03	G	Poor control or frequent exacerbations.	Assess adherence before stepping up therapy.	GINA Severe Asthma Guide	Moderate	Strong	83.3%	Core PMB Care
G-04	G	Smokers or patients with second-hand smoke/vape exposure.	Advise cessation and provide support.	GINA Strategy; WHO respiratory disease guidance	High	Strong	83.3%	Core PMB Care
G-05	G	Poorly controlled asthma.	Assess and treat comorbidities.	GINA Strategy	Moderate	Strong	83.3%	Core PMB Care

ID	Domain	Clinical situation	Recommendation	Source	Certainty of evidence	Strength of recommendation	Consensus	PMB applicability
G-06	G	Symptoms disproportionate to lung function or suspected dysfunctional breathing.	Assess for dysfunctional breathing and refer for respiratory physiotherapy.	GINA Strategy; pulmonary rehabilitation studies	Moderate	Conditional	100%	Specialist-Directed Care
G-07	G	All asthma patients.	Encourage regular physical activity; consider pulmonary rehabilitation in severe asthma.	GINA Strategy	Moderate	Strong	83.3%	Specialist-Directed Care
G-08	G	Allergic asthma.	Identify and reduce relevant allergen/environmental exposures.	GINA Strategy	Low-Moderate	Conditional	83.3%	Core PMB Care
G-09	G	All asthma patients.	Recommend influenza and age-appropriate pneumococcal vaccination.	GINA Strategy; WHO immunisation guidance	Moderate	Strong	83.3%	Core PMB Care

ID	Domain	Clinical situation	Recommendation	Source	Certainty of evidence	Strength of recommendation	Consensus	PMB applicability
G-10	G	All patients with asthma at routine follow-up	Review asthma control, inhaler technique, adherence, exacerbation history and the written asthma action plan at every scheduled asthma review, and adjust treatment according to the patient's current level of control and future risk.	GINA 2025	—	—	***[Blank in manuscript]***	*[Blank in manuscript]*

Part 2 — Supporting Recommendation Matrix

ID	Rationale	Evidence summary	Guideline considerations	URL / reference
A — Prevention / Risk Reduction				
A-01	Smoking and irritant exposure increase symptoms, exacerbation risk and lung function decline; cessation improves outcomes.	GINA emphasises assessment and reduction of risk factors including smoking/vaping and air pollution.	Link to local cessation programmes; consider occupational and household exposures in the South African context.	https://ginasthma.org/wp-content/uploads/2025/11/GINA-Summary-Guide-2025-WEB_FINAL-WMS.pdf
A-02	Targeted trigger remediation can reduce symptoms/exacerbations in sensitized individuals; broad, untargeted measures are less effective.	NAEPP 2020 recommends multicomponent, targeted interventions (e.g., integrated pest management for cockroach/mouse sensitization, mold remediation where dampness/mold is present).	Prioritise feasible, low-cost interventions; avoid recommending costly measures without clear benefit.	https://www.nhlbi.nih.gov/health-topics/asthma-management-guidelines-2020-updates
A-03	Respiratory viral infections are common triggers for exacerbations; vaccination reduces risk of severe infection.	GINA notes exacerbations are often triggered by viral upper respiratory tract infections and emphasises risk-reduction strategies.	Follow NDoH/EML vaccine schedules for indication and dosing.	https://ginasthma.org/wp-content/uploads/2025/11/GINA-Summary-Guide-2025-WEB_FINAL-WMS.pdf
A-04	Irritants and pollution can precipitate symptoms and exacerbations; reducing exposure addresses a modifiable risk factor.	GINA lists exposure to smoking/vaping and air pollution among risk factors to assess and address.	Contextualise to local housing/cooking practices.	https://ginasthma.org/wp-content/uploads/2025/11/GINA-Summary-Guide-2025-WEB_FINAL-WMS.pdf

ID	Rationale	Evidence summary	Guideline considerations	URL / reference
A-05	Ongoing exposure can lead to persistent disease and poorer outcomes; early recognition improves prognosis.	GINA recommends assessing exposures including occupational triggers; if work-related asthma is suspected, exposure should be reduced and specialist assessment arranged.	Link to occupational health pathways; document employer exposure details.	https://ginasthma.org/wp-content/uploads/2025/11/GINA-Summary-Guide-2025-WEB_FINAL-WMS.pdf
A-06	Comorbid conditions contribute to poor control and increased exacerbation risk; addressing them improves outcomes and reduces escalation.	GINA recommends assessing comorbidities and modifiable risk factors as part of the asthma management cycle.	Use integrated chronic disease services where available.	https://ginasthma.org/wp-content/uploads/2025/11/GINA-Summary-Guide-2025-WEB_FINAL-WMS.pdf
A-07	NSAID-triggered bronchospasm can cause severe exacerbations; recognition prevents avoidable attacks.	GINA discusses different asthma phenotypes and the importance of identifying triggers and comorbidities.	Align with local analgesic alternatives and referral capacity.	https://ginasthma.org/wp-content/uploads/2025/11/GINA-Summary-Guide-2025-WEB_FINAL-WMS.pdf
A-08	Education improves adherence, technique, and timely escalation, reducing avoidable exacerbations.	GINA's management cycle includes education and skills training as a core component.	Use standardised education materials and local-language resources; provide a written asthma action plan; check and correct inhaler technique.	https://ginasthma.org/wp-content/uploads/2025/11/GINA-Summary-Guide-2025-WEB_FINAL-WMS.pdf

ID	Rationale	Evidence summary	Guideline considerations	URL / reference
A-09	Obesity and physical inactivity worsen asthma symptoms, dyspnoea perception and exacerbation risk; improving fitness and reducing weight improves control and quality of life.	GINA recognises obesity and inactivity as modifiable risk factors; clinical studies show weight reduction and improved fitness are associated with better symptom control, improved quality of life and reduced healthcare utilisation.	Avoid advising activity restriction; instead optimise controller therapy and provide a pre-exercise reliever/anti-inflammatory strategy where needed; address dysfunctional breathing and deconditioning separately from bronchoconstriction.	https://ginasthma.org/wp-content/uploads/2025/11/GINA-Summary-Guide-2025-WEB_FINAL-WMS.pdf
A-10	Patients who recognise worsening asthma early and adjust treatment appropriately have fewer severe exacerbations and emergency department visits.	Self-management education with a written action plan consistently reduces hospitalisations, ED visits and severe exacerbations across multiple populations.	Include symptom recognition, reliever escalation, when to start oral corticosteroids (if applicable), and when to seek urgent care; provide in the local language and ensure patient understanding.	https://ginasthma.org
A-11	Incorrect inhaler technique and poor adherence are among the most common causes of uncontrolled asthma and preventable exacerbations.	Studies show a large proportion of patients use inhalers incorrectly; correcting technique and improving adherence frequently restores control without escalation to high-dose therapy or biologics.	Demonstrate technique using the patient's own device; document assessment method (observation, pharmacy refill, or device counter); always check before diagnosing severe asthma.	https://ginasthma.org/wp-content/uploads/2025/11/GINA-Summary-Guide-2025-WEB_FINAL-WMS.pdf

ID	Rationale	Evidence summary	Guideline considerations	URL / reference
A-12	Immunotherapy modifies allergic airway inflammation and may reduce symptoms, medication use and exacerbations in appropriately selected allergic asthma.	NAEPP 2020 supports subcutaneous immunotherapy as an adjunct treatment for allergic asthma, and sublingual dust-mite immunotherapy in selected patients with sensitisation and persistent symptoms.	Only for confirmed allergic phenotype, not for uncontrolled severe asthma; requires a trained provider and monitoring for systemic reactions. ***CAC voting note: CAC feedback: treatment options and eligibility criteria still to be discussed — high-cost treatment option. Rationale: high cost, unregistered treatment; not considered PMB level of care; cost-effectiveness and affordability not yet determined.***	https://www.nhlbi.nih.gov/health-topics/asthma-management-guidelines-2020-updates
B — Pharmacology (Chronic Management)				
B-01	Airway inflammation is present even in mild asthma; a reliever containing inhaled corticosteroid treats both bronchoconstriction and underlying inflammation, reducing severe exacerbations and preventing over-reliance on short-acting bronchodilators.	Randomised and pragmatic trials comparing as-needed low-dose ICS-formoterol with SABA-only therapy consistently demonstrate a significant reduction in severe exacerbations, similar or improved symptom control, and lower cumulative corticosteroid exposure.	Use a formoterol-containing ICS inhaler (fast-onset LABA required); check inhaler technique at initiation; provide a written asthma action plan; align with formulary availability; ensure the selected ICS-formoterol device is licensed for AIR/MART use.	https://www.nice.org.uk/guidance/ng245 ; https://ginasthma.org/

ID	Rationale	Evidence summary	Guideline considerations	URL / reference
B-02	MART increases anti-inflammatory exposure at the time of symptom worsening while maintaining a simple regimen, reducing severe exacerbations without increasing overall corticosteroid exposure and avoiding SABA-only rescue reliance; the goal is prevention of attacks rather than merely symptom relief.	ICS–formoterol reliever-based strategies significantly reduce severe exacerbations compared with SABA-reliever regimens and are at least comparable to daily maintenance ICS for symptom control. Key trials — SYGMA-1 (O'Byrne 2018, Lancet), SYGMA-2 (Bateman 2018, NEJM), Novel START (Beasley 2019, NEJM) and PRACTICAL (Hardy 2019, Lancet Respiratory Medicine) — all demonstrated reduced severe exacerbations compared with SABA-reliever pathways.	Explain clearly that this inhaler is both preventer and reliever; review at 4–8 weeks; document reliever-use frequency. **Manuscript editorial note: B? merge B02 and B16????/**	https://www.nice.org.uk/guidance/ng245

ID	Rationale	Evidence summary	Guideline considerations	URL / reference
B-03	The step from low-dose to medium-dose MART is not based on one pivotal RCT but on a coherent body of trials showing a dose–response anti-inflammatory effect, reduction in exacerbations, and preservation of the reliever anti-inflammatory strategy.	SYGMA-1 (O'Byrne et al., Lancet 2018) showed as-needed budesonide-formoterol reduced severe exacerbations versus SABA; SYGMA-2 (Bateman et al., NEJM 2018) showed as-needed ICS-formoterol was non-inferior to maintenance ICS for exacerbations; the PRACTICAL trial (Hardy et al., Lancet Respiratory Medicine) supports increasing inhaled corticosteroid exposure to improve inflammation control while maintaining anti-inflammatory reliever treatment, although trial heterogeneity prevents high-certainty grading.	Confirm adherence and inhaler technique before escalation; ensure a licensed ICS/formoterol MART device; address comorbidities and exposures; check for over-reliance on reliever doses; align with local formulary and access. **Manuscript editorial note: BB-03 + B-17 Both state: Escalate to medium-dose MART. Keep only one.**	https://www.nice.org.uk/guidance/ng245
B-04	Most apparent treatment failure is caused by modifiable factors — poor technique, poor adherence, ongoing exposures, misdiagnosis, and uncontrolled comorbidities — rather than medication inefficacy.	Observational and specialist-clinic studies show a large proportion of "uncontrolled asthma" achieves control after correcting adherence, technique, and comorbidities; guidelines consistently recommend confirming diagnosis and addressing these factors before escalating beyond medium-dose therapy.	Check inhaler technique/adherence; ensure the chosen ICS/formoterol is licensed for AIR/MART; align with local formulary and access; document reassessment (audit requirement); repeat spirometry where available.	https://www.nice.org.uk/guidance/ng245

ID	Rationale	Evidence summary	Guideline considerations	URL / reference
B-05	Only formoterol-containing combinations have sufficiently rapid onset to function safely as a reliever; the choice of specific product depends on national licensing, formulary access and device availability rather than comparative clinical efficacy, so using a non-licensed device risks off-label prescribing.	Formoterol has a rapid bronchodilator onset comparable to SABA while providing prolonged effect; other LABAs (e.g., salmeterol) are not suitable relievers. NICE NG245 specifies that AIR therapy should be delivered using an ICS–formoterol inhaler licensed for this indication; not every budesonide-formoterol product is licensed for PRN use internationally. No RCTs directly compare licensed versus unlicensed prescribing; certainty derives from pharmacovigilance principles, dosing safety and the regulatory approval trials for the product itself.	Do not use an ICS-formoterol reliever with a non-formoterol maintenance LABA inhaler; provide device-specific counselling; use teach-back for inhaler technique.	https://www.nice.org.uk/guidance/ng245
B-06	Both strategies provide anti-inflammatory exposure and reduce exacerbation risk compared with SABA-only treatment, balancing reduction in exacerbations with treatment burden/adherence realities in mild disease; intermittent ICS may suit patients with infrequent symptoms who are unlikely to take daily ICS reliably, provided they can be taught to use ICS whenever SABA is used.	The NHLBI/NAEPP focused update concluded that, in mild persistent asthma, both daily low-dose ICS and intermittent ICS taken with SABA reduce exacerbations compared with SABA-only regimens; the intermittent strategy is supported by trial data but requires patient understanding and reliable technique, hence a conditional recommendation.	Do not mix tracks — if using AIR/MART, do not also prescribe SABA as the default reliever; intermittent ICS-with-SABA requires clear written instructions and teach-back; contextualise to local availability, licensing and affordability (SA formulary constraints); reassess control within 6–8 weeks.	https://www.nhlbi.nih.gov/health-topics/asthma-management-guidelines-2020-updates

ID	Rationale	Evidence summary	Guideline considerations	URL / reference
B-07	SMART/MART reduces severe exacerbations and cumulative systemic corticosteroid exposure compared with traditional step-up strategies that retain SABA-only reliever therapy.	NAEPP/NHLBI 2020 synthesised multiple RCTs showing fewer exacerbations with SMART/MART versus comparator regimens (higher-dose ICS + SABA, or same-dose ICS-LABA + SABA), leading the panel to issue a strong recommendation with explicitly stated high certainty for ≥12 years.	Educate on maximum daily inhalations; use only formoterol-containing combinations. **Manuscript editorial note: B-07 + B-13 + B-14 All three essentially say: Track 1 preferred. ICS-formoterol preferred. AIR preferred. I would keep one recommendation: For adolescents and adults, the preferred treatment pathway is Track 1 using ICS-formoterol as the reliever, with escalation from AIR to MART according to asthma control.**	https://www.nhlbi.nih.gov/health-topics/asthma-management-guidelines-2020-updates

ID	Rationale	Evidence summary	Guideline considerations	URL / reference
B-08	Maintaining anti-inflammatory reliever therapy reduces severe exacerbations and preserves treatment simplicity.	Randomised controlled trials comparing SMART/MART to maintenance ICS-LABA plus SABA reliever showed significantly fewer severe exacerbations, lower oral corticosteroid exposure, and similar or slightly improved symptom control; benefits were consistent across pragmatic and blinded trials, forming the basis for a strong recommendation in NAEPP 2020.	Avoid reverting to SABA-only rescue; confirm adherence and triggers before escalation; applies to Step 3 and Step 4 therapy; only formoterol-containing ICS-LABA combinations are suitable (rapid-onset LABA required); educate patients about maximum daily inhalations; align with local formulary/licensing. **Manuscript editorial note: delete B08, it is incorporated into B07 / B-08 is not really a standalone recommendation — it is an implementation principle that naturally belongs with B-07. The aim is to make B-07 the definitive recommendation on the preferred Track 1 pathway.**	https://www.nhlbi.nih.gov/health-topics/asthma-management-guidelines-2020-updates

ID	Rationale	Evidence summary	Guideline considerations	URL / reference
B-09	Adding a LAMA provides additional bronchodilation via a different pharmacologic pathway (anticholinergic), improving lung function and symptoms when inflammation-targeted therapy alone is insufficient, though benefits on control/quality of life are modest and the exacerbation benefit is less certain.	Randomised trials of tiotropium added to ICS-LABA showed modest improvement in FEV_1, small improvement in symptom control, and some (inconsistent) reduction in exacerbations; benefits were clinically meaningful but smaller than those seen with MART strategies.	Applies to patients using the SABA-reliever strategy; consider inhaler device burden, adherence and patient values; ensure correct inhaler technique before escalation; if already on MART, prefer MART optimisation rather than LAMA first (MART pathway: low-dose MART → medium-dose MART → assess → specialist referral; traditional pathway: ICS → ICS/LABA → ICS/LABA + LAMA → referral).	https://www.nhlbi.nih.gov/health-topics/asthma-management-guidelines-2020-updates
B-10	In poorly controlled patients, regular ICS provides more reliable anti-inflammatory control than PRN-only strategies; even patients with infrequent symptoms have underlying airway inflammation and remain at risk of severe exacerbations, whereas SABA-only treatment addresses bronchoconstriction but not inflammation.	Randomised trials and population studies show lower severe exacerbations, reduced emergency visits and hospitalisations, reduced oral corticosteroid exposure, and lower asthma mortality risk with ICS-containing reliever therapy versus SABA-only.	Guideline applies to very mild/mild asthma; verify age cut-offs and local access to budesonide/formoterol; SABA-only therapy should no longer be used as chronic management; educate patients about over-reliance on reliever inhalers. **Manuscript editorial note: B-10 + B-22 Both say: Avoid SABA-only therapy. Keep B-22 because it is clearer.**	https://cts-sct.ca/wp-content/uploads/2021/03/2021-CTS-Guideline-very-mild-and-mild-asthma.pdf

ID	Rationale	Evidence summary	Guideline considerations	URL / reference
B-11	As-needed ICS-formoterol provides inhaled corticosteroid exposure whenever symptoms occur, reducing exacerbation risk in patients who do not reliably take maintenance ICS, functioning as a pragmatic harm-reduction strategy while ongoing adherence counselling continues; certainty is low not because the treatment is ineffective, but because almost no RCTs have specifically randomised adolescents alone, subgroup analyses dominate, adherence behaviour confounds results, and outcomes are extrapolated from adult mild-asthma trials.	Randomised trials in mild asthma demonstrated that as-needed budesonide/formoterol, compared with daily ICS plus SABA, significantly reduced severe exacerbations, provided similar overall symptom control, resulted in lower cumulative corticosteroid exposure, and improved safety in patients with inconsistent adherence.	Verify age cut-offs and local access to budesonide/formoterol; adherence counselling must still be provided; not a substitute for education and inhaler-technique review; particularly useful in adolescents and young adults; requires a formoterol-containing ICS inhaler.	https://cts-sct.ca/wp-content/uploads/2021/03/2021-CTS-Guideline-very-mild-and-mild-asthma.pdf

ID	Rationale	Evidence summary	Guideline considerations	URL / reference
B-12	This is a risk-reduction strategy for adolescents who often have low symptom burden but remain at substantial risk of severe exacerbations; providing inhaled corticosteroid exposure reduces risk even when day-to-day symptoms appear minimal, though certainty is low because direct adolescent-only RCT data are limited and evidence is largely extrapolated from adult mild-asthma trials and subgroup analyses.	Evidence in adolescents is largely extrapolated from mild-asthma trials and subgroup analyses; direct adolescent-only RCT data are limited, leading to indirectness and imprecision, but population data demonstrate higher exacerbation risk in this age group, supporting a preventive ICS-containing strategy despite low certainty.	Verify age cut-offs and local access to budesonide/formoterol; use shared decision-making; address adherence behaviour explicitly; particularly relevant in adolescents with SABA over-use; verify local availability of budesonide/formoterol products. **Manuscript editorial note: I would actually remove this. Why? The adolescent recommendation is already covered by the general Track 1 recommendation. It doesn't add a new PMB principle.**	https://cts-sct.ca/wp-content/uploads/2021/03/2021-CTS-Guideline-very-mild-and-mild-asthma.pdf
B-13	Reliever therapy containing inhaled corticosteroid treats both bronchoconstriction and airway inflammation during symptom episodes, reducing severe exacerbations, emergency visits and systemic corticosteroid exposure compared with SABA-only reliever approaches.	PICO framework: adolescents/adults with asthma; Track-1 ICS–formoterol reliever-based strategy versus SABA-reliever strategy; outcomes of severe exacerbations, ED visits/hospitalisation, symptom control, oral steroid exposure and adverse events; assessed over approximately 6–12 months in major RCTs and pragmatic trials.	High-level treatment-strategy framework rather than a step-up therapy; align with local formulary and licensing for reliever/controller use and ensure inhaler technique and access to an approved ICS–formoterol product. **Manuscript editorial note: Delete, it duplicates B01 and B07. There is no new PMB principle.**	https://ginasthma.org/wp-content/uploads/2025/11/GINA-Summary-Guide-2025-WEB_FINAL-WMS.pdf

ID	Rationale	Evidence summary	Guideline considerations	URL / reference
B-14	The emphasis is on preventing severe exacerbations while matching real-world adherence patterns; the reliever itself delivers anti-inflammatory therapy, reducing reliance on SABA-only treatment.	PICO framework: mild asthma; as-needed low-dose ICS–formoterol versus SABA-only or daily low-dose ICS + SABA; outcomes of severe exacerbations, OCS bursts, ED visits and symptom control over 6–12 months.	Step 1–2 guidance; overlaps with AIR-based strategies recommended in NG245, CTS and SA NEMLC; align with local formulary licensing for reliever/controller use. **Manuscript editorial note: Delete, duplicate of B01, no new information.**	https://ginasthma.org/wp-content/uploads/2025/11/GINA-Summary-Guide-2025-WEB_FINAL-WMS.pdf
B-15	Regular SABA-only use increases exacerbation risk and mortality; pairing SABA with ICS ensures anti-inflammatory treatment whenever bronchoconstriction symptoms occur and reduces severe exacerbations compared with SABA-only use.	PICO framework: mild asthma on Track 2; SABA with concomitant ICS (separate or combination, depending on regimen) versus SABA alone; outcomes of exacerbations/ED visits and symptom control over 6–12 months.	If Track 2 is chosen, clinicians must actively instruct patients to take ICS whenever SABA is used and monitor refill frequency to detect SABA over-reliance.	https://ginasthma.org/wp-content/uploads/2025/11/GINA-Summary-Guide-2025-WEB_FINAL-WMS.pdf
B-16	MART reduces severe exacerbations by linking reliever use to delivery of inhaled corticosteroid, providing early anti-inflammatory treatment during symptom worsening; it is a continuation of the same pharmacologic strategy rather than a new escalation.	PICO framework: uncontrolled asthma on Step 1–2; low-dose MART versus fixed-dose ICS/LABA + SABA reliever; outcomes of severe exacerbations, ED visits/hospitalisation and symptom control over 6–12 months.	Step 3 guidance; overlaps with MART recommendations in NG245. **Manuscript editorial note: Delete, duplicates B-02.**	https://ginasthma.org/wp-content/uploads/2025/11/GINA-Summary-Guide-2025-WEB_FINAL-WMS.pdf

ID	Rationale	Evidence summary	Guideline considerations	URL / reference
B-17	Increasing the maintenance ICS dose while continuing the same anti-inflammatory reliever strategy escalates controller therapy and improves exacerbation prevention without returning the patient to SABA-reliever-based treatment.	PICO framework: uncontrolled asthma on Step 3; medium-dose MART versus higher-dose fixed ICS/LABA + SABA; outcomes of exacerbations, ED visits/hospitalisation and adverse events over 6–12 months.	Step 4 guidance; this is a dose escalation within the same reliever-based pathway, not a switch to traditional step-up therapy; overlaps with MART recommendations in NG245; confirm inhaler technique, adherence and triggers before escalation. **Manuscript editorial note: Delete, duplicates B-03.**	https://ginasthma.org/wp-content/uploads/2025/11/GINA-Summary-Guide-2025-WEB_FINAL-WMS.pdf
B-18	Asthma is an inflammatory disease even in mild presentations; regular or symptom-triggered exposure to inhaled corticosteroid reduces severe exacerbations, whereas SABA-only treatment is associated with increased attack risk and hospitalisation — the same anti-inflammatory-exposure principle applied to children.	Evidence across paediatric RCTs and large observational cohorts consistently shows higher exacerbation risk and healthcare utilisation in children treated with SABA-only regimens.	Paediatric principle (6–11 years); ensure age-appropriate inhaler/device and dosing (usually spacer with MDI); review technique regularly; provide a written action plan to caregivers.	https://ginasthma.org/wp-content/uploads/2025/11/GINA-Summary-Guide-2025-WEB_FINAL-WMS.pdf

ID	Rationale	Evidence summary	Guideline considerations	URL / reference
B-19	As-needed ICS/formoterol provides inhaled corticosteroid exposure at the time of symptoms, improving real-world anti-inflammatory coverage and potentially reducing exacerbations in patients with poor adherence to daily controller therapy; feasibility and access are key considerations for public-sector implementation.	The SA NEMLC evidence review evaluated as-needed budesonide/formoterol versus daily low-dose ICS + SABA in ≥12-year-old patients with mild persistent asthma; across randomised and pragmatic studies, severe exacerbations and OCS courses were reduced, overall symptom control was similar, cumulative ICS exposure was lower, and real-world adherence was better, though symptom-control scores were sometimes slightly inferior to strict daily ICS.	Align with current STG/EML; specify inhaler formulation (e.g., budesonide/formoterol DPI vs pMDI) and clearly document maximum daily doses (important medico-legal point); provide a written asthma action plan; particularly suitable for patients with documented poor adherence to daily ICS.	https://www.health.gov.za/wp-content/uploads/2025/12/Evidence-Review-ICS-formoterol-for-asthma_consolidated-report-27-November-2025.pdf
B-20	Most patients with uncontrolled asthma do not have severe asthma; poor adherence, incorrect inhaler technique, smoking, obesity, rhinitis, GERD and occupational exposures commonly explain poor control, and confirming optimisation prevents unnecessary biologic therapy and inappropriate long-term escalation.	Observational cohorts show that when adherence and inhaler technique are corrected, a large proportion of "uncontrolled" asthma patients achieve control without biologics; severe asthma prevalence falls from approximately 15–20% of referred patients to 3–5% after structured assessment. No RCTs randomise patients to "assessment versus no assessment" (unethical), so evidence derives from implementation studies and specialist severe-asthma clinics.	Before referral, document spirometry confirmation of asthma, adherence assessment, inhaler technique check, smoking status, rhinitis/sinus disease, GERD, obesity, occupational exposure, correct dosing of ICS-formoterol, and at least 3 months of optimised therapy; without this documentation, biologic eligibility is not established.	https://ginasthma.org/wp-content/uploads/2025/11/GINA-2025-Global-Strategy-for-Asthma-Management-and-Prevention.pdf

ID	Rationale	Evidence summary	Guideline considerations	URL / reference
B-21	LAMA provides additional bronchodilation via a different pharmacologic pathway (anticholinergic blockade of airway smooth muscle); it improves lung function and modestly reduces exacerbations in patients uncontrolled on ICS-LABA, while being substantially less costly and lower risk than biologic therapy, and this step confirms treatment-refractory disease before escalation to specialist biologics.	Randomised controlled trials (PrimoTinA-asthma, MezzoTinA-asthma and related studies) demonstrated improved FEV_1, improved symptom control, and a modest reduction in exacerbations, though effect size was smaller than for biologics. Kerstjens HAM et al. (PrimoTinA-asthma, NEJM 2012) showed tiotropium improved lung function and reduced exacerbations in severe asthma; Peters SP et al. (JACI 2010) compared tiotropium with salmeterol add-on to ICS.	Before referral, ensure confirmed adherence, correct inhaler technique, adequate ICS dose, and a LAMA trial of at least approximately 8–12 weeks.	https://ginasthma.org/wp-content/uploads/2025/11/GINA-2025-Global-Strategy-for-Asthma-Management-and-Prevention.pdf
B-22	Bronchodilator-only relief treats bronchospasm but not airway inflammation and is associated with increased exacerbation risk; pairing reliever use with ICS provides anti-inflammatory treatment at symptom onset.	Guideline pathways describe two tracks — anti-inflammatory reliever (preferred) and SABA-reliever — and evidence consistently shows ICS-containing reliever strategies reduce severe exacerbations compared with SABA-only use.	Provide explicit written instructions; monitor SABA refill frequency (a marker of poor control); do not mix Track-1 and Track-2 reliever advice. **Manuscript editorial note: See B-10 — B-22 is clearer (keep this one).**	https://ginasthma.org/
B-23	LTRA provides anti-inflammatory benefit but is less effective than inhaled corticosteroids for preventing exacerbations.	Guidelines include LTRA in stepwise pathways; studies demonstrate smaller exacerbation reduction compared with ICS, and safety warnings require patient counselling and follow-up.	Document counselling about mood, sleep and behavioural changes; review early after initiation; do not substitute for checking inhaler technique and adherence.	https://www.nice.org.uk/guidance/ng245

ID	Rationale	Evidence summary	Guideline considerations	URL / reference
B-24	Immunotherapy targets the allergic disease driver and may reduce symptoms and exacerbations in selected patients.	Guidelines identify HDM SLIT as an add-on option for selected allergic asthma patients, not a replacement for controller therapy.	Confirm sensitisation and clinical relevance; ensure adherence and inhaler technique are optimised first; specialist supervision recommended. **CAC voting note: CAC feedback: treatment options and eligibility criteria still to be discussed — high-cost treatment option. Rationale: high cost, unregistered treatment; not considered PMB level of care; cost-effectiveness/affordability not yet determined; evidence certainty rated moderate.**	https://ginasthma.org/
B-25	Reduces steroid exposure and adverse effects while maintaining control.	Guidelines recommend planned dose reduction once control is achieved, with monitoring and an action plan; baseline control should be documented before step-down.	Choose a stable period (no infection or travel); document baseline control before step-down; provide a written asthma action plan and follow-up.	https://ginasthma.org/
B-26	These options may reduce exacerbations in selected severe asthma patients when standard therapy is insufficient, but require careful patient selection and safety monitoring.	Severe asthma guidance describes these add-on options after optimisation and phenotype assessment.	Requires specialist supervision; consider antimicrobial stewardship and safety monitoring for azithromycin; not first-line therapy.	https://ginasthma.org/

ID	Rationale	Evidence summary	Guideline considerations	URL / reference
B-27	These therapies are associated with higher adverse effects and inferior exacerbation prevention compared with ICS-containing regimens.	Modern strategies emphasise anti-inflammatory treatment; bronchodilator-only management and outdated therapies increase morbidity.	Document the reason if exceptional use occurs; reinforce that SABA may still be prescribed, but never without ICS exposure.	https://ginasthma.org/
C — Diagnosis				
C-01	Objective confirmation of asthma reduces the substantial harm of misdiagnosis — including unnecessary long-term treatment or missed alternative diagnoses — because asthma is frequently over- and under-diagnosed on symptoms alone.	GINA recommends confirming the diagnosis and documenting objective evidence in the medical record whenever feasible. Demonstration of variable airflow limitation (e.g., bronchodilator reversibility or PEF variability) is the defining diagnostic feature; biomarkers such as FeNO or blood eosinophils may support but cannot independently confirm the diagnosis.	If already on ICS, additional tests or step-adjustment may be needed to confirm; record objective evidence in the medical record; low FeNO does not exclude asthma; avoid long-term treatment without diagnostic confirmation where feasible.	https://ginasthma.org/wp-content/uploads/2025/11/GINA-Asthma-Summary-Guide-2025-WEB_FINAL-WMS.pdf

ID	Rationale	Evidence summary	Guideline considerations	URL / reference
C-02	Type-2 inflammation biomarkers (FeNO, blood eosinophils) can support the diagnosis in the appropriate clinical context, but lack sufficient specificity and sensitivity to independently confirm or exclude asthma.	The NICE/BTS/SIGN NG245 diagnostic pathway recommends FeNO or blood eosinophils early in the adult diagnostic process to facilitate treatment decisions in primary care; elevated FeNO (≥50 ppb) is associated with eosinophilic airway inflammation and corticosteroid responsiveness, but patients should still proceed to spirometry or PEF monitoring where available.	FeNO availability varies; if unavailable, proceed directly to the spirometry/PEF pathway. Low FeNO does not exclude asthma; smoking may lower FeNO; allergic rhinitis may elevate FeNO. **CAC voting note: CAC feedback: FeNO not considered PMB level of care in the asthma diagnostic work-up; not widely available in South Africa; low FeNO does not exclude asthma; more clinical utility in non-responders or paediatric patients where spirometry is difficult.**	https://www.nice.org.uk/guidance/ng245/resources/asthma-diagnosis-monitoring-and-chronic-asthma-management-bts-nice-sign-pdf-66143958279109
C-03	Demonstrating variable airflow obstruction with bronchodilator reversibility testing confirms the defining physiological feature of asthma and distinguishes it from alternative conditions (e.g., COPD, dysfunctional breathing, cardiac disease), whereas diagnosing without objective testing risks significant harm from lifelong unnecessary medication or a missed alternative diagnosis.	NG245 sets the bronchodilator-reversibility threshold for diagnosis in adults and children 5–16; diagnostic accuracy studies show spirometry with bronchodilator reversibility significantly improves diagnostic certainty compared with symptom assessment alone, while biomarkers (FeNO, eosinophils) estimate inflammatory phenotype but cannot confirm airflow variability.	Ensure appropriate bronchodilator withholding times and quality spirometry technique/calibration; if normal but suspicion remains, repeat when symptomatic or perform PEF monitoring/bronchial challenge; document results in the medical record.	https://www.nice.org.uk/guidance/ng245/resources/asthma-diagnosis-monitoring-and-chronic-asthma-management-bts-nice-sign-pdf-66143958279109

ID	Rationale	Evidence summary	Guideline considerations	URL / reference
C-04	PEF monitoring can demonstrate variable airflow limitation as a practical alternative when spirometry is inaccessible, but its accuracy depends on patient technique and adherence and it has lower specificity than spirometry, which remains the preferred confirmatory test when available.	NG245 recommends 2-week PEF monitoring with a 20% variability threshold when spirometry cannot be performed; studies show PEF variability correlates with reversible airflow obstruction and improves diagnostic certainty over symptoms alone, though it is effort-dependent and less reproducible than spirometry.	Provide written instructions and demonstrate correct technique; use the same meter throughout the monitoring period; record morning and evening readings before bronchodilator use; interpret results alongside symptoms; arrange spirometry confirmation when feasible.	https://www.nice.org.uk/guidance/ng245/resources/asthma-diagnosis-monitoring-and-chronic-asthma-management-bts-nice-sign-pdf-66143958279109
C-05	Bronchial challenge testing is highly accurate for detecting airway hyperresponsiveness and acts as a diagnostic tie-breaker when routine tests are inconclusive, but it is reserved as a conditional option because it requires specialist facilities, has limited availability, and carries procedural risk and contraindications.	NG245 recommends bronchial challenge testing when diagnostic doubt persists after standard objective testing; studies demonstrate high sensitivity and strong negative predictive value, helping exclude asthma when results are normal, though the test must be performed in specialised settings, limiting universal applicability.	Requires a specialist setting; assess contraindications (severe airflow obstruction, recent MI, uncontrolled hypertension, pregnancy considerations depending on test); withhold bronchodilators before testing; particularly useful when alternative diagnoses are being considered. **CAC voting note: CAC feedback: bronchial challenge testing is highly specialised and not considered PMB level of care in the asthma diagnostic work-up.**	https://www.nice.org.uk/guidance/ng245/resources/asthma-diagnosis-monitoring-and-chronic-asthma-management-bts-nice-sign-pdf-66143958279109

ID	Rationale	Evidence summary	Guideline considerations	URL / reference
C-06	Objective testing improves diagnostic accuracy in children, where symptom-based diagnosis alone frequently causes over- and under-diagnosis; FeNO is particularly useful for identifying corticosteroid-responsive (Type-2) inflammation but cannot independently confirm or exclude asthma, so physiologic confirmation via spirometry or PEF remains necessary when uncertainty persists.	NG245's paediatric diagnostic pathway places FeNO (35 ppb threshold) as the first objective investigation because it is feasible in children and helps guide treatment decisions; studies show FeNO has good predictive value for eosinophilic asthma but limited specificity, so spirometry demonstrating reversible airflow obstruction remains necessary when diagnostic uncertainty persists.	Interpret FeNO alongside clinical history and features; allergic rhinitis, atopy, and viral infections may affect FeNO/lung function results; refer for specialist assessment if ongoing diagnostic doubt.	https://www.nice.org.uk/guidance/ng245/resources/asthma-diagnosis-monitoring-and-chronic-asthma-management-bts-nice-sign-pdf-66143958279109
C-07	Because reliable objective lung-function testing is usually not feasible in preschool children and viral-induced wheeze is heterogeneous with a high risk of over-diagnosis, a monitored ICS trial with regular review balances timely symptom control against inappropriate long-term labelling.	NG245 and international asthma strategies recommend a monitored ICS trial in preschool children with recurrent wheeze; observational and cohort studies show response to anti-inflammatory therapy helps identify children likely to have persistent asthma, though treatment response alone does not definitively confirm the diagnosis, so follow-up and reassessment are essential.	Avoid labelling asthma without follow-up; provide safety-net advice and a written action plan to caregivers; review response within 4–8 weeks; consider alternative diagnoses if poor response (e.g., viral wheeze, airway malacia, aspiration, cystic fibrosis, foreign body).	https://www.nice.org.uk/guidance/ng245/chapter/recommendations

ID	Rationale	Evidence summary	Guideline considerations	URL / reference
C-08	Maintaining asthma control during pregnancy is important because poorly controlled asthma is associated with maternal hypoxia, pre-eclampsia, preterm birth, low birth weight, and fetal complications, whereas inhaled corticosteroids have not been shown to increase congenital malformation risk and bronchial provocation testing carries risk without being required for immediate management.	GINA advises continuing ICS-containing treatment in pregnancy and deferring bronchial provocation testing until after delivery; observational and registry studies show maternal exacerbations and hypoxia are associated with adverse fetal outcomes, whereas ICS therapy is considered safe in pregnancy.	Coordinate care with antenatal providers; monitor control closely and review more frequently during pregnancy; reinforce adherence and inhaler technique; provide a written action plan; post-partum, reconsider objective confirmation of the diagnosis.	https://ginasthma.org/wp-content/uploads/2025/11/GINA-Asthma-Summary-Guide-2025-WEB_FINAL-WMS.pdf
C-09	Controller therapy can suppress airway variability and produce false-negative objective tests, so normal spirometry while on treatment should not be used alone to exclude asthma.	Guidelines note that prior ICS exposure reduces bronchodilator reversibility and airway variability, lowering diagnostic sensitivity; objective confirmation should still be pursued when feasible.	Document current therapy at time of testing; avoid unsafe withdrawal in high-risk patients; repeat testing if symptoms recur.	—
C-10	Airflow limitation during an acute episode may be transient and non-specific, so confirming the diagnosis with objective testing after clinical recovery improves diagnostic accuracy.	Follow-up spirometry after exacerbation improves differentiation between asthma, viral bronchospasm, and alternative diagnoses.	Record exacerbation severity, treatment required, and triggers; ensure a follow-up appointment is scheduled before discharge from acute care.	—

ID	Rationale	Evidence summary	Guideline considerations	URL / reference
C-11	Early identification prevents irreversible airway disease and has medico-legal implications.	Serial PEF monitoring showing variability between work and rest days is a validated diagnostic method for occupational asthma.	Ask about improvement on weekends/leave; document occupation and exposures; early referral is important.	—
C-12	Asthma and COPD may coexist, and failure to recognise overlap leads to inappropriate treatment.	Guidelines recommend clinical judgment using variability, atopy, exacerbation pattern, and steroid responsiveness to distinguish phenotypes.	Document smoking history, age of onset, and symptom variability; consider specialist referral if uncertain.	—
C-13	Not all wheeze and dyspnoea represent asthma, and misdiagnosis leads to unnecessary treatment escalation.	Studies show a significant proportion of patients labelled with 'uncontrolled asthma' have breathing pattern disorders rather than airway inflammation.	Features suggesting ILO include inspiratory noise, throat tightness, sudden onset/offset, and normal spirometry; avoid unnecessary medication escalation.	—
C-14	Asthma is a variable disease, so objective confirmation may be historical or treatment-response based when current testing is inconclusive.	GINA allows diagnosis based on documented variability in lung function over time or significant improvement following anti-inflammatory therapy.	Ensure improvement is clinically meaningful and not due to bronchodilator alone; record dates and measurements clearly. **Manuscript editorial note: Move this up to under C-05.**	—
C-15	Clear documentation prevents diagnostic drift, inappropriate PMB classification, and treatment errors.	Guidelines emphasise recording objective evidence and the diagnostic method used.	Include spirometry values, PEF variability, or challenge test results; record smoking, atopy, and occupational risk.	—

ID	Rationale	Evidence summary	Guideline considerations	URL / reference
D — Monitoring / Follow-up				
D-01	Symptom control and future exacerbation risk are independent domains, and patients with minimal symptoms can still be at high risk of severe or life-threatening exacerbations, so regular structured review enables early identification of deterioration and timely treatment adjustment.	GINA recommends reassessing both symptom control and future exacerbation risk at every visit and at least once a year; structured monitoring has been associated with improved asthma control, fewer exacerbations, and more appropriate treatment adjustment.	Integrate into chronic care visits; flag high-risk patients for more frequent review.	https://ginasthma.org/wp-content/uploads/2025/11/GINA-Asthma-Summary-Guide-2025-WEB_FINAL-WMS.pdf
D-02	Asthma outcomes are driven by future risk (severe exacerbations, hospitalisation, lung function decline) as well as by daily symptoms, and regular structured assessment of established predictors — such as prior exacerbations, SABA overuse, and poor inhaler technique — identifies high-risk patients early and enables targeted risk reduction.	International asthma strategies consistently recommend assessment of both symptom control and future risk factors at each review; large real-world cohort studies (e.g., the SABINA programme; Nwaru BI et al., European Respiratory Journal, 2020) show SABA overuse predicts exacerbations and mortality, and a Cochrane review (Normansell R et al.) shows interventions to improve inhaler technique improve outcomes.	Use a standardised review template; include ICU/intubation history as a high-risk marker.	https://ginasthma.org/wp-content/uploads/2025/11/GINA-Asthma-Summary-Guide-2025-WEB_FINAL-WMS.pdf

ID	Rationale	Evidence summary	Guideline considerations	URL / reference
D-03	Asthma symptoms alone do not reliably reflect airway obstruction, so periodic objective lung-function monitoring is required to detect decline and guide treatment adjustment before severe exacerbations occur.	GINA recommends spirometry (or PEF if unavailable) before starting ICS, 3–6 months later, then every 1–2 years; reduced lung function (particularly low FEV1) is a well-established predictor of severe exacerbations and hospitalisation and forms part of international asthma risk stratification.	Where spirometry is limited, use PEF with symptom tracking and ensure quality control.	https://ginasthma.org/wp-content/uploads/2025/11/GINA-Asthma-Summary-Guide-2025-WEB_FINAL-WMS.pdf
D-04	Asthma exacerbations are frequently preceded by recognisable worsening symptoms or reduced peak flow, so providing patients with clear written instructions enables early treatment adjustment and timely healthcare utilisation, preventing progression to severe attacks, with large benefit and negligible harm or cost.	Randomised trials and systematic reviews (Gibson PG et al., Cochrane Database of Systematic Reviews) demonstrate that structured asthma self-management education combined with a written action plan reduces emergency department visits, hospitalisation, and exacerbations, and improves quality of life compared with usual care.	Use locally approved templates; include emergency contact details and medication step instructions.	https://ginasthma.org/wp-content/uploads/2025/11/GINA-Asthma-Summary-Guide-2025-WEB_FINAL-WMS.pdf

ID	Rationale	Evidence summary	Guideline considerations	URL / reference
D-05	Incorrect inhaler technique, found in 30–80% of patients in studies, leads to inadequate drug delivery, poor asthma control, and inappropriate treatment escalation, so direct observation and correction improve medication effectiveness and prevent unnecessary escalation.	Systematic reviews on inhaler technique education (e.g., Normansell R et al., Cochrane Database of Systematic Reviews) show incorrect inhaler use is common and associated with worse asthma control and increased exacerbations, while educational interventions with demonstration and repeated checking improve clinical outcomes.	Prefer devices the patient can use correctly; consider spacers for pMDIs; before escalating therapy (e.g., increasing ICS dose, adding LABA, referring, or considering biologics), confirm the patient is actually receiving the medication correctly. **Manuscript editorial note: Reviewer proposed inserting a new D-06 here: "Spacer use — Patients using a pressurised metered-dose inhaler (pMDI). Recommend the use of a spacer with a pressurised metered-dose inhaler, particularly in children and in adults who have difficulty coordinating inhalation, to improve medication delivery and reduce oropharyngeal adverse effects." Note: this is a proposed NEW recommendation, not a description of the existing D-05/D-06 rows — the existing D-06 in the matrix is about reassessing modifiable causes before escalating therapy and is unaffected.**	https://ginasthma.org/wp-content/uploads/2025/11/GINA-Asthma-Summary-Guide-2025-WEB_FINAL-WMS.pdf

ID	Rationale	Evidence summary	Guideline considerations	URL / reference
D-06	Many patients with apparently uncontrolled asthma have modifiable factors driving symptoms rather than truly treatment-resistant disease, so checking these fundamentals before escalating avoids overtreatment and prevents unnecessary exposure to high-dose corticosteroids or advanced therapies.	GINA advises checking these fundamentals before stepping up therapy, distinguishing 'difficult-to-treat' from 'severe' asthma; studies of difficult-to-treat asthma demonstrate that correcting modifiable factors frequently restores control without intensifying pharmacotherapy.	Document findings; consider referral if uncertainty persists.	https://ginasthma.org/wp-content/uploads/2025/11/GINA-Asthma-Summary-Guide-2025-WEB_FINAL-WMS.pdf
D-07	Abrupt withdrawal of ICS increases the risk of loss of control and exacerbations, so a structured, gradual step-down with close monitoring of symptoms, reliever use, and lung function reduces relapse risk while minimising medication burden.	GINA recommends step-down when stable and warns against abruptly stopping ICS, aiming to identify the minimum effective anti-inflammatory therapy while maintaining protection against severe exacerbations; a systematic review (Rank MA et al., Journal of Allergy and Clinical Immunology, 2013) and other evidence indicate ICS withdrawal or large dose reductions are associated with higher rates of loss of control and exacerbations compared with maintaining low-dose ICS, while gradual, monitored reduction can be achieved safely in many stable patients.	Ensure an action plan and follow-up are in place before dose reduction; do not step down during high-risk periods (recent exacerbation, respiratory infection, pregnancy, poor adherence, ongoing smoking exposure, or anticipated poor follow-up); confirm fundamentals first (diagnosis secure, inhaler technique correct, adherence good, comorbidities managed); provide/refresh the written action plan and schedule follow-up (e.g., 4–8 weeks after change).	https://ginasthma.org

ID	Rationale	Evidence summary	Guideline considerations	URL / reference
D-08	FeNO reflects Type-2 (eosinophilic) airway inflammation and correlates with corticosteroid responsiveness, helping risk-stratify patients and guide ICS decisions in appropriate contexts, but its values are influenced by confounders such as atopy, allergic rhinitis, smoking, and recent steroid use, and it cannot independently confirm or exclude asthma or replace objective lung function testing.	NAEPP 2020 focused updates include recommendations on FeNO for diagnosis and monitoring; randomised controlled studies show FeNO-guided management can reduce exacerbations and assist ICS titration in selected patients, particularly those with Type-2 inflammatory asthma, and diagnostic accuracy studies show FeNO improves probability estimation when spirometry is non-diagnostic, though sensitivity is insufficient to exclude asthma when FeNO is low.	Availability/cost may limit use; low FeNO does not exclude asthma; high FeNO predicts better response to ICS; smoking lowers FeNO (false low); allergic rhinitis raises FeNO (false high); recent steroid use suppresses FeNO. Suggested adult interpretation thresholds: <25 ppb eosinophilic inflammation unlikely, 25–50 ppb indeterminate, ≥50 ppb eosinophilic inflammation likely.	https://www.nhlbi.nih.gov/health-topics/asthma-management-guidelines-2020-updates
D-09	SABA overuse is one of the strongest predictors of severe exacerbations and asthma death.	Large cohort studies consistently show increased hospitalisation and mortality with SABA overuse.	Pharmacy refill data is useful; do not escalate to LABA before ensuring anti-inflammatory therapy is optimised.	https://ginasthma.org
D-10	Poor adherence is the most common cause of uncontrolled asthma.	Studies show many patients labelled with 'severe asthma' have poor adherence rather than refractory disease.	Avoid judgemental questioning; check cost, beliefs, side-effects, and device issues.	https://ginasthma.org
D-11	The risk of recurrence is highest soon after an attack.	Post-exacerbation review reduces relapse and hospital readmission.	Adjust maintenance therapy and reinforce the action plan.	https://ginasthma.org

ID	Rationale	Evidence summary	Guideline considerations	URL / reference
D-12	Comorbidities commonly drive persistent symptoms despite appropriate therapy.	Treating comorbid conditions improves asthma control and reduces exacerbations.	Particularly important before diagnosing severe asthma.	https://ginasthma.org
D-13	Trigger exposure maintains airway inflammation and impairs control.	Avoidance strategies improve symptom control and reduce medication need.	Ask specifically about workplace symptoms.	https://ginasthma.org
D-14	Viral infections are a major trigger of exacerbations.	Influenza vaccination reduces asthma exacerbations and healthcare use.	Particularly important in children and the elderly.	https://ginasthma.org
D-15	Psychosocial factors strongly influence adherence and outcomes.	Depression and low health literacy correlate with poor asthma control.	Consider simplified action plans and caregiver involvement.	https://ginasthma.org

ID	Rationale	Evidence summary	Guideline considerations	URL / reference
D-16	Some persistent symptoms are due to dysfunctional breathing rather than airway inflammation.	Breathing retraining improves symptoms and quality of life in selected patients.	Particularly useful in adolescents and in patients with frequent 'uncontrolled but normal spirometry' presentations. **CAC voting note: CAC feedback recorded verbatim: "Biologics are high-cost drugs and not PMB of level of care." (Note: this rationale text appears mismatched to D-16 in the source voting sheet — D-16 is Physical activity and rehabilitation/physiotherapy, not a biologic; likely a copy-paste artifact in the CAC's spreadsheet. Flagged for the CMS team to verify against the original voting record rather than silently corrected here.)**	https://ginasthma.org
D-17	These patients have an increased risk of fatal asthma.	GINA lists these as major predictors of asthma mortality.	Should trigger a referral pathway (link to severe asthma section).	https://ginasthma.org
E — Exacerbations (Acute Asthma)				
E-01	Early bronchodilation and correction of hypoxaemia reduce the risk of deterioration, and severity grading directs the appropriate level of escalation.	GINA advises assessing severity while starting SABA and oxygen therapy, including monitoring of SpO2 and lung function.	Align oxygen targets with local protocols; ensure adequate and correct spacer/nebuliser technique.	https://ginasthma.org/wp-content/uploads/2025/11/GINA-Summary-Guide-2025-WEB_FINAL-WMS.pdf

ID	Rationale	Evidence summary	Guideline considerations	URL / reference
E-02	Misattributing atypical or poorly responsive breathlessness to asthma alone delays definitive management and increases risk.	GINA recommends considering alternative causes of acute breathlessness.	Use local red-flag pathways; consider imaging/ECG where indicated.	https://ginasthma.org/wp-content/uploads/2025/11/GINA-Summary-Guide-2025-WEB_FINAL-WMS.pdf
E-03	Routine testing rarely changes management and increases cost and exposure, and antibiotics are not indicated unless bacterial infection is suspected.	GINA advises against routine chest X-ray, blood gases, and antibiotics in typical exacerbations.	If severe or poor response, consider ABG/VBG and imaging per protocol.	https://ginasthma.org/wp-content/uploads/2025/11/GINA-Summary-Guide-2025-WEB_FINAL-WMS.pdf
E-04	Sedation can precipitate hypoventilation, worsen hypercapnia and ventilation in severe bronchospasm, and complicate recognition of deterioration.	GINA explicitly advises against using sedatives during exacerbation management.	If intubation is required, proceed in a controlled critical care setting with experienced staff.	https://ginasthma.org/wp-content/uploads/2025/11/GINA-Summary-Guide-2025-WEB_FINAL-WMS.pdf
E-05	Close monitoring detects deterioration early and guides safe disposition decisions.	GINA recommends frequent monitoring and lung function reassessment at 1 hour, with escalation if response is poor.	Define escalation triggers locally (SpO2, fatigue, rising CO2, silent chest).	https://ginasthma.org/wp-content/uploads/2025/11/GINA-Summary-Guide-2025-WEB_FINAL-WMS.pdf
E-06	This approach reduces relapse risk and addresses the drivers of exacerbation, including adherence, technique, and trigger exposure.	GINA's management cycle includes education, an action plan, and reassessment after exacerbations.	Link follow-up to primary care/chronic services; document the exacerbation as a high-risk marker.	https://ginasthma.org/wp-content/uploads/2025/11/GINA-Summary-Guide-2025-WEB_FINAL-WMS.pdf

ID	Rationale	Evidence summary	Guideline considerations	URL / reference
E-07	Severe exacerbations can occur even with infrequent symptoms, so risk is not reliably captured by symptom control alone; this is one of the strongest predictors of future severe asthma attacks in primary care databases, and a structured risk review identifies high-risk patients early and enables targeted interventions.	GINA recommends assessing symptom control and future risk separately and quantifying reliever use, noting that excessive SABA dispensing thresholds (>=3 canisters/year; >=12/year) signal increased risk.	Use dispensing/refill records where available; reliever overuse should trigger reassessment of diagnosis, technique, adherence, exposures, comorbidities, and adequacy of ICS-containing therapy.	—
E-08	Immediate transfer prevents deterioration and delays to definitive care.	GINA states: 'Arrange immediate transfer... if there are signs of severe exacerbation.'	Define 'severe signs' per local triage/ED protocol; include drowsy/confused/silent chest as ICU triggers.	https://ginasthma.org/wp-content/uploads/2025/11/GINA-Summary-Guide-2025-WEB_FINAL-WMS.pdf
E-09	Combined bronchodilation and anti-inflammatory therapy reduces the risk of admission and disease progression.	GINA's acute care instructions and ipratropium evidence statement indicate that ipratropium combined with SABA reduces admission risk compared with SABA alone.	Ensure correct delivery method (pMDI plus spacer preferred where feasible); align steroid choice/dose with local standard treatment guideline.	https://ginasthma.org/wp-content/uploads/2025/11/GINA-Summary-Guide-2025-WEB_FINAL-WMS.pdf
E-10	Systemic corticosteroids reduce relapse/recurrence and speed recovery.	GINA provides adult and child dosing and indicates OCS as standard therapy for non-mild exacerbations.	Document each OCS course; multiple short courses compound harm, so optimise inhaled therapy post-event.	https://ginasthma.org/wp-content/uploads/2025/11/GINA-Summary-Guide-2025-WEB_FINAL-WMS.pdf

ID	Rationale	Evidence summary	Guideline considerations	URL / reference
E-11	IV magnesium sulfate provides adjunct bronchodilation in refractory severe attacks.	GINA explicitly includes IV magnesium sulfate as an option in poor responders.	Use local ED dosing/contraindications protocol; monitor vitals and reflexes per protocol.	https://ginasthma.org/wp-content/uploads/2025/11/GINA-Summary-Guide-2025-WEB_FINAL-WMS.pdf
E-12	Titrated oxygen avoids hypoxaemia while minimising the risk of hyperoxia.	GINA provides explicit oxygen saturation targets for acute exacerbation management.	Pulse oximetry may overestimate saturation in hypoxaemia in patients with dark skin; use clinical context and pre-defined escalation thresholds.	https://ginasthma.org/wp-content/uploads/2025/11/GINA-Summary-Guide-2025-WEB_FINAL-WMS.pdf
E-13	Most asthma deaths occur after delayed escalation or premature discharge, so objective reassessment after initial treatment identifies patients at risk of rapid deterioration and prevents unsafe discharge.	GINA recommends reassessment after initial therapy using lung function, oxygenation, clinical status, and risk factors to determine safe disposition; patients with persistent airflow limitation, hypoxaemia, or high-risk features require admission or higher-level care.	Use PEF where spirometry is unavailable; document response to bronchodilator therapy; record prior ICU/intubation history before discharge; arrange early follow-up (within 2-7 days); provide a written asthma action plan.	—

ID	Rationale	Evidence summary	Guideline considerations	URL / reference
E-14	A severe exacerbation is a strong predictor of future severe attacks and death risk, and most preventable contributors (inadequate anti-inflammatory therapy, poor technique/adherence, ongoing exposures, untreated comorbidities, lack of an action plan) can be identified and corrected immediately after an event.	GINA emphasises that exacerbation risk must be assessed separately from symptom control and that a recent severe exacerbation is a key high-risk marker; it recommends optimisation of ICS-containing treatment, technique/adherence review, action plan provision, and early follow-up to prevent relapse and future severe outcomes.	Treat 'recent severe exacerbation' as a high-risk status for at least the next 3-12 months. Minimum documentation set after exacerbation: number of OCS bursts/ED/hospital/ICU in past 12 months; baseline and post-event lung function if available (FEV1/PEF); reliever use pattern; technique check; adherence verification method; trigger/exposure review; comorbidity screen (rhinitis/sinusitis, GERD, obesity/OSA, smoking/vaping, anxiety/dysfunctional breathing). Escalate care/refer if: ICU/intubation history, recurrent ED/hospitalisation, or persistently low lung function.	https://ginasthma.org/wp-content/uploads/2025/11/GINA-Summary-Guide-2025-WEB_FINAL-WMS.pdf
F — Specialist Therapies / Severe Asthma				

ID	Rationale	Evidence summary	Guideline considerations	URL / reference
F-01	Step 5 is primarily a structured reassessment and phenotyping step before escalation, since many 'severe asthma' labels reflect difficult-to-treat asthma driven by modifiable factors, and correcting these prevents unnecessary escalation.	P: severe asthma uncontrolled on Step 4; I: add-on LAMA/biologics plus optimized ICS/LABA; C: optimized ICS/LABA alone; O: exacerbations, oral corticosteroid requirement, quality of life, lung function, adverse events; T: 6-12 months. GINA Step 5 requires systematic reassessment and phenotyping prior to add-on treatment, with add-on therapies considered only after optimized ICS-LABA therapy and confirmation of persistent Type 2 or non-Type 2 disease.	Specialist domain covering add-on therapies including biologics and LAMA, and minimising oral corticosteroids. Document objective diagnosis, inhaler technique check, adherence verification, trigger assessment, and comorbidity screening (rhinitis, sinusitis, obesity, GERD, OSA, smoking exposure); add-on therapy should follow phenotype confirmation and eligibility criteria. **Manuscript editorial note: Duplication between F-01, F-02, F-03, F-06, F-07 and F-08 — all deal with referral, specialist assessment, phenotyping and eligibility for advanced therapies. Reviewer suggests streamlining considerably.**	https://ginasthma.org/wp-content/uploads/2025/11/GINA-Summary-Guide-2025-WEB_FINAL-WMS.pdf

ID	Rationale	Evidence summary	Guideline considerations	URL / reference
F-02	Specialist assessment improves diagnostic certainty and enables targeted therapy, reducing exacerbations and OCS exposure, since most patients with uncontrolled asthma do not have true severe asthma but rather difficult-to-treat asthma due to incorrect diagnosis, poor adherence, incorrect inhaler technique, persistent triggers/exposures, or untreated comorbidities.	GINA recommends phenotype assessment and consideration of add-on therapies at Step 5, with structured severe-asthma assessment including confirmation of diagnosis, optimisation of basic management, and phenotyping prior to initiating add-on biologic therapy; severe asthma is defined only after modifiable factors are corrected and control remains poor on optimized high-dose ICS-LABA therapy.	Consider access to biomarkers and referral pathways; use consistent phenotype definitions and locally specified cut-offs; document baseline exacerbation rate, number of OCS bursts in the last 12 months, prior ICU/intubation history, baseline FEV1, and adherence assessment method (pharmacy refill, interview, or device counter); ensure optimization before biologic approval.	https://ginasthma.org/wp-content/uploads/2025/11/GINA-Summary-Guide-2025-WEB_FINAL-WMS.pdf

ID	Rationale	Evidence summary	Guideline considerations	URL / reference
F-03	Biologic therapies target specific inflammatory pathways (IgE-mediated or eosinophilic Type-2 inflammation) and, when used in correctly phenotyped severe asthma, substantially reduce exacerbations and oral corticosteroid exposure while improving disease control.	GINA discusses severe asthma phenotypes and add-on biologic options in Step 5 care (P: severe asthma uncontrolled on high-dose ICS-LABA; I: add-on biologic therapy [anti-IgE, anti-IL5/5R, anti-IL4R-alpha]; C: optimized ICS-LABA +/- non-biologic add-ons; O: exacerbations, oral corticosteroid dependence, quality of life, lung function; T: 24-52 weeks). Key trials include omalizumab (INNOVATE), mepolizumab (DREAM, MENSA, SIRIUS), benralizumab (SIROCCO, CALIMA), and dupilumab (LIBERTY ASTHMA QUEST, VENTURE).	Consider local availability and cost; ensure adherence and comorbidity optimisation before biologics. Biologics should only be initiated once diagnosis is confirmed (spirometry +/- reversibility), adherence is assessed, inhaler technique is corrected, comorbidities (rhinitis, GERD, obesity, OSA) are treated, environmental exposures are addressed, frequent exacerbations are documented, and Type-2 inflammation is demonstrated via acceptable phenotype markers (blood eosinophils, FeNO, IgE with allergen sensitisation). **CAC voting note: CAC feedback: high-cost treatment option — strict, clear eligibility criteria required; PMB level of care still to be discussed.**	https://ginasthma.org/wp-content/uploads/2025/11/GINA-Summary-Guide-2025-WEB_FINAL-WMS.pdf
F-04	LAMA add-on can improve lung function and reduce exacerbations in selected patients by adding bronchodilation via a different pathway, with its positioning depending on phenotype, device burden, and service pathways.	NAEPP 2020 focused updates include recommendations on LAMA use with ICS for long-term management and include LAMA add-on recommendations; GINA includes LAMA among non-biologic add-ons in difficult-to-treat/severe asthma pathways.	Check inhaler device burden and technique; consider triple therapy inhalers if available; ensure correct device use and persistence; define a trial period (e.g., 8-12 weeks) and response criteria; align with formulary and inhaler availability; GINA emphasises continuing optimization of basics throughout.	https://www.nhlbi.nih.gov/health-topics/asthma-management-guidelines-2020-updates

ID	Rationale	Evidence summary	Guideline considerations	URL / reference
F-05	Benefits are limited to selected patients and the procedures carry risks, so bronchial thermoplasty and other advanced interventions require specialist expertise and structured follow-up.	Specialist care pathways in major guidelines reserve procedural/advanced therapies for selected severe asthma; GINA positions bronchial thermoplasty as a consideration in non-responders and flags limited long-term evidence and the need for a registry.	Likely limited availability; document shared decision-making and alternatives tried; ensure centre capability; maintain a registry/follow-up plan.	https://ginasthma.org/wp-content/uploads/2025/11/GINA-Summary-Guide-2025-WEB_FINAL-WMS.pdf
F-06	Misclassifying difficult-to-treat asthma as severe asthma is one of the most common failures in review submissions; biologic/OCS escalation is justified only for true severe asthma, not for modifiable poor control.	The GINA Severe Asthma pathway defines severe asthma only after systematic optimization and confirmation steps.	Define and standardize local definitions in the PMB guideline (what counts as 'optimized', how adherence is verified, how exacerbation frequency is counted).	https://ginasthma.org/wp-content/uploads/2025/11/GINA-Severe-Asthma-Guide-2025-WEB-FINAL-WMS.pdf

ID	Rationale	Evidence summary	Guideline considerations	URL / reference
F-07	A standardized minimum dataset prevents inappropriate escalation and makes add-on therapy decisions auditable and defensible.	Severe asthma pathways require standardized assessment and documented eligibility before add-ons.	Minimum dataset (suggested fields for the PMB template): objective diagnosis (spirometry +/- bronchodilator reversibility; consider alternative diagnoses); symptom control tool (ACT/ACQ) plus reliever use; exacerbation count (OCS bursts in past 12 months; ED/hospital/ICU); baseline lung function (FEV1 %predicted and/or PEF); adherence verification method (pharmacy refill/device counter/structured interview); inhaler technique checked.	https://ginasthma.org/wp-content/uploads/2025/11/GINA-Severe-Asthma-Guide-2025-WEB-FINAL-WMS.pdf
F-08	Reviewers will challenge biologic approvals unless a transparent eligibility algorithm is shown, since explicit eligibility criteria are required to operationalize the pathway.	GINA recommends phenotype-directed add-ons, and eligibility criteria are required to operationalize the pathway.	PMB guideline should explicitly define: biomarker thresholds used locally (eosinophils/FeNO/IgE sensitisation); exacerbation threshold (e.g., >=2 bursts/year and/or hospitalization); OCS dependence definition (maintenance OCS or frequent bursts); and contraindications/precautions and 'not eligible' cases (poor adherence, wrong diagnosis, uncontrolled exposures). **CAC voting note: CAC feedback: biomarker cut-offs to be adopted locally — still to be discussed in detail.**	https://ginasthma.org/wp-content/uploads/2025/11/GINA-Severe-Asthma-Guide-2025-WEB-FINAL-WMS.pdf

ID	Rationale	Evidence summary	Guideline considerations	URL / reference
F-09	Structured response review prevents indefinite high-cost therapy without benefit and ensures measurable outcomes.	Severe asthma care requires structured follow-up and reassessment after add-on therapy.	Define 'response' using at least: reduction in exacerbations/OCS bursts; reduced maintenance OCS dose (if applicable); improved ACT/ACQ; improved lung function or PEF stability; reduced SABA use/improved symptom burden. If inadequate response: re-check diagnosis/adherence/phenotype and consider an alternate biologic class or non-Type-2 pathway. **Manuscript editorial note: Merge F-09 and F-12, then delete F-12.**	https://ginasthma.org/wp-content/uploads/2025/11/GINA-Severe-Asthma-Guide-2025-WEB-FINAL-WMS.pdf
F-10	OCS toxicity is a major quality/safety and medico-legal risk, so reviewers often demand explicit mitigation strategies.	Severe asthma pathways emphasize minimizing OCS exposure and using add-ons to reduce OCS burden in appropriate patients.	Include a required checklist if OCS is used: indication and planned duration; bone protection plan (risk assessment plus prophylaxis where indicated); metabolic monitoring (BP, glucose, weight); infection risk and vaccination status considered; psychiatric/mood effects counseling.	—

ID	Rationale	Evidence summary	Guideline considerations	URL / reference
F-11	In selected adults, macrolide add-on can reduce exacerbations, but requires risk-benefit assessment and stewardship safeguards.	P: adults with severe asthma and frequent exacerbations; I: add-on azithromycin (specialist-supervised); C: standard care without macrolide; O: exacerbations, quality of life, adverse events (QT, hearing), antimicrobial resistance; T: approximately 6-12 months.	Follow local antimicrobial stewardship; monitor ECG/QT risk and drug interactions and hearing symptoms; define stop rules if no benefit is seen.	https://ginasthma.org/wp-content/uploads/2025/11/GINA-Severe-Asthma-Guide-2025-WEB-FINAL-WMS.pdf
F-12	Biologics are high-cost and phenotype-dependent, so structured response assessment prevents ineffective long-term use and supports a rational switching strategy.	P: severe asthma starting biologic; I: biologic initiation plus structured assessment/stop-switch algorithm; C: biologic initiation without defined response evaluation; O: exacerbations, OCS reduction, quality of life, lung function, continuation rates, adverse events; T: 3-12 months.	Define local response criteria (exacerbations/OCS/quality of life/FEV1); ensure adherence remains verified; track biomarkers consistently; document payer approval requirements.	—
G — Non-Pharmacologic (Foundational) Asthma Management				
G-01	Asthma is a variable disease requiring patient self-management, and structured education with an action plan supports this.	Written action plans combined with education reduce hospitalisations, ED visits, oral steroid use, and days off work/school.	Include green/yellow/red zones and reliever frequency thresholds; review annually.	—

ID	Rationale	Evidence summary	Guideline considerations	URL / reference
G-02	Incorrect inhaler technique causes inadequate drug delivery and apparent treatment failure.	Up to 70% of patients misuse inhalers; correcting technique improves control and reduces exacerbations without changing medication.	Use the teach-back method; recheck after medication changes; use a spacer for pMDI where appropriate.	—
G-03	Non-adherence is a leading cause of uncontrolled asthma.	Many 'severe asthma' cases achieve control once adherence improves.	Review pharmacy refills and dose counters, and use non-judgmental questioning.	—
G-04	Smoking increases airway inflammation and steroid resistance.	Smoking is associated with more exacerbations, reduced ICS response, and accelerated lung function decline.	Offer behavioural and pharmacologic cessation support; document exposure.	—
G-05	Comorbid conditions worsen symptoms and exacerbation risk.	Treating rhinitis and OSA improves control and reduces reliever use.	Evaluate rhinitis/sinusitis, obesity, GERD, OSA, and anxiety/depression; weight loss is beneficial.	—
G-06	Some 'uncontrolled asthma' is actually a breathing pattern disorder rather than airway inflammation.	Breathing retraining improves dyspnoea perception, quality of life, and reliever use.	Refer if normal spirometry with severe symptoms, frequent reliever use, exercise dyspnoea, or inducible laryngeal obstruction; do not use routine secretion-clearance physiotherapy.	—
G-07	Exercise improves conditioning and symptom perception.	Physical activity is associated with improved exercise tolerance, quality of life, and asthma control scores.	Encourage routine activity; consider pulmonary rehabilitation for severe disease.	—

ID	Rationale	Evidence summary	Guideline considerations	URL / reference
G-08	Targeted avoidance reduces exacerbations in sensitised individuals.	Dust-mite covers, smoking avoidance, and occupational exposure control are beneficial.	Focus on confirmed triggers rather than blanket avoidance.	—
G-09	Respiratory infections are major exacerbation triggers.	Influenza vaccination reduces severe exacerbations and hospitalisation.	Give annual influenza vaccination; give pneumococcal vaccination per age/risk.	—
G-10	Not present in the working recommendation matrix; sourced directly from the manuscript's Appendix E table.	—	**— Note: This row appears in the manuscript's live Appendix E table (page 70) but is not present in the working evidence matrix. Its Consensus % and PMB applicability cells are blank in the manuscript itself — not a CAC-voting-record gap, but genuinely unrecorded.**	—

Appendix F: Diagnostic and Treatment Algorithms for Asthma

Step	Diagnostic pathway
1	Identify a history of variable respiratory symptoms (e.g. wheeze, shortness of breath, chest tightness and cough) and assess for characteristic triggers
2	Perform spirometry with bronchodilator reversibility testing where available to confirm variable expiratory airflow limitation.
3	If spirometry is unavailable, undertake PEF monitoring with a symptom diary and arrange spirometry when feasible
4	Where available, use FeNO and/or blood eosinophil count as adjunctive investigations to support phenotyping or treatment decisions. Biomarkers should not be used alone to confirm or exclude asthma.
5	If diagnostic uncertainty persists despite initial assessment, refer for specialist evaluation and bronchial challenge testing where appropriate.
6	Document the objective evidence supporting the diagnosis and the basis for assigning a long-term diagnosis of asthma wherever feasible
Step	**Treatment adjustment pathway**
1	Initiate an ICS-containing treatment strategy appropriate for the patient's age, clinical status and formulary, and provide a personalised written asthma action plan.
2	e Review symptom control, future exacerbation risk, adherence, inhaler technique and treatment response 1–3 months after treatment initiation or any treatment change.
3	Before stepping up treatment, reassess diagnosis, adherence, inhaler technique, environmental exposures and comorbidities and address modifiable factors.
4	Escalate treatment within the ICS-formoterol/MART or Track 2 pathway according to age, clinical status, treatment response and formulary considerations.
5	Refer patients with difficult-to-treat or severe asthma for specialist assessment before initiating advanced add-on therapies.
6	. Consider step-down therapy after sustained good asthma control (generally ≥3 months), while avoiding complete withdrawal of inhaled corticosteroid therapy unless clinically indicated.

These algorithms should be interpreted together with the detailed recommendations contained in Sections A–G and adapted to individual patient characteristics, age, comorbidities, medication availability and the applicable PMB benefit structure.

Appendix G: Monitoring Tools and Action Plan Templates

The monitoring tool and personalised asthma action plan are intended to support ongoing assessment of asthma control, future exacerbation risk, treatment optimisation, patient self-management, and follow-up. The format may be adapted according to the patient's age, literacy level, preferred language and individual clinical circumstances.

Review domain	Document at each visit
Asthma Control	Daytime symptoms, night waking, activity limitation, reliever use and exacerbations. And overall symptom control.
Future Risk	Prior ICU/intubation, steroid bursts, low lung function, high SABA use, poor adherence and exposures and previous hospitalisation. Previous ICU admission or intubation, exacerbations requiring oral corticosteroids, emergency department visits or hospitalisation, low lung function (where available), frequent reliever use, poor adherence, incorrect inhaler technique and ongoing environmental exposures.
Technique/adherence Inhaler Technique and Adherence	Observed inhaler technique, adherence barriers, prescription refill history (where available), dose counters and patient understanding of treatment.
Comorbidities	Comorbidities that may adversely affect asthma control, including rhinitis/sinusitis, GERD, obesity, OSA, anxiety/depression and smoking/vaping exposure.
Management Plan	Medication adjustments, update of the written asthma action plan, follow-up arrangements, and indications for escalation or specialist referral where appropriate.

Asthma action plan core fields

- Usual controller and reliever instructions.
- Green/yellow/red zone symptoms or PEF thresholds.
- When to increase reliever/controller therapy.
- When to start oral corticosteroids if prescribed by clinician.
- When to seek urgent care or call emergency services.
- Follow-up and emergency contacts.
- What to do if symptoms fail to improve or worsen despite following the action plan.(The action plan includes instructions for situations in which symptoms do not improve or worsen after the initial treatment steps.)

Personalised Asthma Action Plan – Minimum Core Components

The written asthma action plan should include:

- The patient's usual controller and reliever medication, including doses and frequency.
- Green, yellow and red zone instructions based on symptoms and/or peak expiratory flow (PEF), where applicable.
- Clear instructions on when and how to increase reliever and/or controller therapy.

- Instructions on when to commence oral corticosteroids if previously prescribed by the treating clinician.
- Clear guidance on when to seek urgent medical attention or activate emergency medical services.
- Follow-up arrangements and emergency contact details.
- Instructions on what to do if symptoms fail to improve or continue to worsen despite following the action plan.
- The written asthma action plan should be reviewed, reinforced and updated at every routine asthma review and following every exacerbation or significant treatment change.

Implementation Barriers and Mitigation Strategies

While this guideline's diagnostic and treatment algorithms are designed to be broadly applicable, their successful implementation in South African practice depends on local resource availability. The barriers below reflect the constraints most likely to be encountered across South African primary and specialist care settings, together with a corresponding mitigation strategy for each. Where relevant, the strategy is anchored to a specific recommendation already contained in this guideline (cross-referenced by recommendation ID).

Implementation barrier	Mitigation strategy	Cross-ref.
Limited spirometry (and FeNO) access in primary care	Use the PEF-based alternative diagnostic pathway (2-week twice-daily PEF monitoring with a validated meter and symptom diary, ≥20% variability threshold) where spirometry cannot be performed or is delayed, followed by spirometry confirmation once access becomes available. Prioritise spirometry (and, where feasible, FeNO) access expansion at high-volume primary-care sites; FeNO should not be treated as a gating requirement for diagnosis or treatment initiation.	**C-04**
ICS–formoterol / MART inhaler availability and cost	Align PMB entitlement with SA EML-listed ICS/formoterol alternatives and phase in MART funding by PMB applicability tier. Where an ICS-formoterol reliever is unavailable or unaffordable, revert to the guideline's stated fallback of daily low-dose ICS plus SABA reliever, depending on local STG/EML decisions, inhaler availability and patient adherence.	**B-19**
Workforce capacity for structured asthma education	Task-share structured education, written action-plan development, and inhaler-technique assessment/training to trained nurses and pharmacists rather than relying solely on physician time. Use standardised, pre-formatted written asthma action-plan templates to reduce per-encounter clinician burden and support consistent delivery at every initiation and follow-up visit.	**G-01, G-02**

Implementation barrier	Mitigation strategy	Cross-ref.
Referral pathways to specialist / severe-asthma services in under-resourced areas	Formalise Step 5 referral criteria and triage instructions (diagnostic uncertainty, severe exacerbations, occupational asthma, difficult-to-treat/severe asthma, or advanced therapies requiring specialist evaluation) so referrals are timely and appropriately prioritised. Where specialist services are geographically limited, extend virtual/telehealth specialist review for phenotype assessment and add-on therapy (e.g., LAMA, biologics) decisions to reduce travel burden and waiting times.	**F-01, F-04**

These barriers and strategies should be reviewed and updated as part of the guideline's scheduled review cycle, informed by implementation feedback from CAC/TWG members and treating clinicians.

Appendix H: PMB Minimum Service Package/ PMB Service Package and Benefit Entitlements

The PMB service package describes the **minimum benefit entitlements** for the diagnosis, treatment and ongoing management of asthma in accordance with the Medical Schemes Act and its Regulations. It represents the minimum level of care that must be funded where PMB requirements are met and **should not be interpreted as limiting access to additional clinically appropriate investigations, treatments or services where these are reasonably required based on the individual patient's clinical circumstances.**

Component	Minimum PMB package
Clinical Assessment	Comprehensive history and physical examination, confirmation of diagnosis where feasible, assessment of asthma control, future exacerbation risk, inhaler technique, adherence, comorbidities, and appropriate clinical documentation.
Diagnostics Services	Objective diagnostic assessment including spirometry with bronchodilator reversibility where available peak expiratory flow (PEF), PEF monitoring where appropriate, pulse oximetry induring acute care and targeted investigations where clinically indicated.
Medicines and devices	ICS-containing treatment strategies, appropriate reliever therapy, spacer devices where indicated, systemic corticosteroids for acute exacerbations, and access to oxygen therapy and bronchodilator delivery systems for emergency management.
Education Patient Education and Self-Management	Inhaler technique, adherence support and written action plan. Structured asthma education, inhaler technique assessment and training, adherence support, personalised written asthma action plan, and counselling regarding trigger avoidance and self-management.

Component	Minimum PMB package
Monitoring and Follow-up	Scheduled clinical review, reassessment of asthma control and future risk, inhaler technique and adherence review, lung function monitoring where available, and structured post-exacerbation follow-up.
Referral Referral Pathways	Specialist pathways for diagnostic uncertainty, severe exacerbations, occupational asthma and difficult-to-treat/severe asthma. Referral for specialist assessment where there is diagnostic uncertainty, severe or life-threatening exacerbations, suspected occupational asthma, difficult-to-treat asthma, severe asthma, or where advanced therapies require specialist evaluation.
Emergency Care	Assessment and treatment of acute asthma exacerbations, including bronchodilator therapy, systemic corticosteroids, oxygen therapy where indicated, monitoring, appropriate disposition (discharge or admission), and post-exacerbation follow-up.

Appendix I: Evidence Tables

Topic	Evidence summary	Sources
ICS-containing therapy	The source guidelines recommend ICS-containing therapy for confirmed asthma, based on evidence relating to exacerbation reduction, symptom control and severe outcomes. These are the foundation of asthma management because it reduces exacerbations, improves symptom control and lowers the risk of severe outcomes. SABA-only treatment is no longer considered appropriate management for confirmed asthma. High-quality evidence demonstrates that ICS-containing treatment reduces exacerbations, improves symptom control, and decreases the risk of severe asthma outcomes. SABA-only treatment is no longer recommended for patients with confirmed asthma.	GINA 2025; NICE NG245; NAEPP 2020
MART/SMART MART (Maintenance and Reliever Therapy)	Randomised controlled trials and guideline evidence demonstrate that ICS-formoterol MART reduces severe exacerbations and simplifies treatment in eligible patients with moderate to severe asthma.	NICE NG245; NAEPP 2020; GINA 2025
Objective diagnosis	Symptom-only diagnosis risks over- and under-treatment; spirometry/PEF/bronchial challenge document variable airflow limitation and improve diagnostic certainty. Objective testing improves diagnostic accuracy and reduces both over- and under-diagnosis of asthma. Spirometry with bronchodilator reversibility is the preferred test where available. Peak expiratory flow monitoring and bronchial challenge testing remain useful alternatives in selected patients.	NICE NG245; GINA 2025
Written action plans	Self-management education with written action plan reduces severe exacerbations, ED visits and hospitalisation. Structured self-management education supported by a personalised written asthma action plan reduces severe exacerbations, emergency department visits and hospitalisations, and improves self-management.	GINA 2025
Inhaler technique and adherence	Incorrect inhaler technique and poor adherence are commonly associated with reduced asthma control, exacerbations and treatment escalation undertaken before assessment and correction of modifiable factors. Regular assessment and education improve outcomes. Poor inhaler technique and poor adherence are major contributors to uncontrolled asthma and unnecessary treatment escalation.	GINA 2025; Cochrane reviews

Topic	Evidence summary	Sources
	Regular assessment, education and correction improve asthma outcomes.	
Biologics Biologic therapy	In appropriately selected patients with severe Type-2 asthma, biologic therapies reduce exacerbations, improve asthma control and reduce oral corticosteroid exposure. Treatment requires specialist assessment, inflammatory phenotyping, defined eligibility criteria and regular response monitoring	GINA Severe Asthma Guide 2025
FeNO and biomarkers	FeNO and blood eosinophils support phenotyping and treatment decisions in selected patients but should not be used in isolation to confirm or exclude asthma.	NICE NG245; GINA 2025
Spirometry	Spirometry with bronchodilator reversibility remains the preferred objective investigation for confirming variable expiratory airflow limitation and supporting the diagnosis of asthma where available	GINA 2025; NICE NG245
Oral corticosteroid stewardship	Repeated or long-term oral corticosteroid exposure is associated with substantial cumulative morbidity. Current evidence supports minimising maintenance oral corticosteroid use and prioritising steroid-sparing therapies whenever possible.	GINA Severe Asthma Guide 2025
Asthma education and self-management	Structured asthma education improves adherence, inhaler technique, self-management skills and overall asthma outcomes, particularly when combined with a written asthma action plan and regular follow-up.	GINA 2025

Appendix J: Abbreviations and Definitions

Term	Definition
ACO	Asthma–COPD overlap.
ACT	Asthma Control Test.
AIR	Anti-inflammatory reliever therapy.
BDR	Bronchodilator reversibility.
CAC	Clinical Advisory Committee.
ED	Emergency Department.
EtD	Evidence-to-Decision Framework.
FEV_1	Forced expiratory volume in one second.
FeNO	Fractional exhaled nitric oxide.
GERD	Gastro-oesophageal reflux disease.
GINA	Global Initiative for Asthma.
HCP	Healthcare professional. *(Optional if used in the guideline.)*
ICS	Inhaled corticosteroid.
ICS–LABA	Inhaled corticosteroid–long-acting β_2-agonist combination therapy.
ILO	Inducible laryngeal obstruction.
LABA	Long-acting β_2-agonist.
LAMA	Long-acting muscarinic antagonist.
LTRA	Leukotriene receptor antagonist.
MART	Maintenance-and-reliever therapy using ICS–formoterol.
MRA	Maintenance reliever approach. *(Only include if used.)*
NAEPP	National Asthma Education and Prevention Program.
NICE	National Institute for Health and Care Excellence (United Kingdom).
OCS	Oral corticosteroid.
OSA	Obstructive sleep apnoea.
PEF	Peak expiratory flow.
PMB	Prescribed Minimum Benefit.
PROM	Patient-reported outcome measure. *(Only include if used.)*
PREM	Patient-reported experience measure. *(Only include if used.)*

RCT	Randomised controlled trial.
SABA	Short-acting β_2-agonist.
SMART	Single Maintenance and Reliever Therapy (alternative terminology for MART).
SpO_2	Peripheral oxygen saturation measured by pulse oximetry.
Type 2-high asthma	Asthma characterised by Type 2 inflammatory features (e.g., eosinophilic inflammation), often responsive to inhaled corticosteroids and targeted biologic therapies.

Appendix K: Key Clinical Questions

Key questions were derived from the clinical scope of the five source guidelines and the recommendation domains developed by the Clinical Advisory Committee (Appendix E, Domains A–G), and prioritised according to PMB relevance, frequency of the clinical scenario in South African practice, and funding/cost impact.

Each key question is expressed in a structured Population / Intervention / Comparator / Outcome (PICO) format and mapped to the CAC recommendation domain it underpins. The "Priority basis" column records, for each question, why it was included and prioritised

ID	Domain	Population	Intervention	Comparator	Outcome	Priority basis
A — General Principles, Prevention & Non-Pharmacological Care						
KQ-A1	A	All patients with confirmed or suspected asthma	Structured non-pharmacological measures (smoking/vaping cessation advice, environmental/allergen control, vaccination, written education, inhaler-technique training)	Usual care without structured non-pharmacological intervention	Symptom control; exacerbation frequency; Core PMB Care applicability	*High-volume, universally applicable — every patient encounter includes these measures*
KQ-A2	A	Patients with confirmed allergic asthma, clinically relevant sensitisation and persistent symptoms despite optimal standard therapy	Allergen immunotherapy (subcutaneous or sublingual)	Standard pharmacologic therapy alone	Symptom control; exacerbation reduction; Specialist-Care PMB applicability	*Moderate PMB cost impact — Specialist-Care tier; affects a defined allergic-asthma subgroup*
B — Pharmacologic Treatment and Escalation/De-escalation						
KQ-B1	B	Adolescents/adults ≥12y with newly diagnosed or untreated confirmed asthma	As-needed low-dose ICS–formoterol (anti-inflammatory reliever, AIR)	SABA-only reliever therapy	Exacerbation rate; symptom control; Core PMB Care applicability	*Highest-frequency clinical scenario — first-line therapy decision for nearly all new diagnoses*

ID	Domain	Population	Intervention	Comparator	Outcome	Priority basis
KQ-B2	B	Adolescents/adults ≥12y with asthma uncontrolled on as-needed AIR therapy	Low-dose maintenance-and-reliever therapy (MART) using ICS–formoterol	Continued AIR-only therapy, or SABA-only reliever	Exacerbation rate; symptom control; PMB-fundable cost	*High exacerbation-prevention impact; core PMB funding boundary decision*
KQ-B3	B	Patients with uncontrolled persistent asthma despite optimised medium/high-dose ICS-containing therapy	Add-on long-acting muscarinic antagonist (LAMA)	Continued ICS-containing therapy without LAMA	Symptom control; exacerbation reduction; PMB applicability tier (Core vs. Specialist-Directed)	*Moderate-to-high PMB cost impact — add-on therapy funding boundary*
KQ-B4	B	Patients with well-controlled asthma on stable ICS-containing therapy and low exacerbation risk	Gradual step-down of ICS-containing therapy	Continuation of current maintenance dose	Maintained symptom control; exacerbation risk; avoidance of unnecessary medicine cost	*Cost-avoidance priority — prevents unnecessary long-term medicine expenditure*
C — Diagnosis and Objective Confirmation						
KQ-C1	C	Patients of any age with symptoms suggestive of asthma	Objective diagnostic testing (spirometry with bronchodilator reversibility, FeNO/eosinophils, PEF monitoring, or bronchial challenge testing)	Symptom-based diagnosis without objective confirmation	Diagnostic accuracy; avoidance of over-/under-treatment; Diagnostic PMB Service applicability	*Gatekeeping decision for all downstream PMB entitlement; high diagnostic-accuracy impact*

ID	Domain	Population	Intervention	Comparator	Outcome	Priority basis
KQ-C2	C	Patients ≥5y with suspected asthma in settings where spirometry is unavailable or delayed	Alternative objective testing (serial PEF monitoring, FeNO)	Deferred diagnosis pending spirometry access	Diagnostic accuracy; time-to-treatment; feasibility in resource-constrained settings	*High frequency in resource-constrained SA primary care; access/equity priority*
D — Monitoring and Long-Term Follow-up						
KQ-D1	D	All patients with confirmed asthma in routine follow-up	Structured review (symptom control, future risk, adherence, inhaler technique, comorbidities, objective lung function where feasible)	Unstructured/ad hoc review	Sustained symptom control; reduced exacerbation risk; Monitoring PMB Service applicability	*Recurring, high-volume PMB Monitoring Service; core driver of sustained control*
KQ-D2	D	Patients receiving ongoing controller therapy	Fractional exhaled nitric oxide (FeNO) as an adjunct to guide ICS titration	Clinical assessment alone without FeNO	Diagnostic/monitoring accuracy; appropriateness of treatment adjustment; cost of adjunctive testing	*Moderate cost impact — adjunctive test funding boundary*
E — Acute Exacerbation Management						
KQ-E1	E	Patients presenting with acute asthma exacerbation	Severity-based initial management (reliever therapy, oxygen, systemic corticosteroids, escalation criteria)	Undifferentiated management not stratified by severity	Resolution of exacerbation; hospitalisation/ICU avoidance; Acute PMB/Emergency Care applicability	*High clinical urgency and Acute PMB/Emergency Care cost impact*

ID	Domain	Population	Intervention	Comparator	Outcome	Priority basis
KQ-E2	E	Patients discharged after treatment for an acute exacerbation	Structured post-exacerbation review (within 2–7 days) with ICS-containing therapy optimisation and action-plan update	Standard discharge without structured early follow-up	Reduced repeat exacerbation/hospitalisation; sustained control	*High re-exacerbation/hospitalisation-prevention impact*
F — Specialist Care, Difficult-to-Treat and Severe Asthma						
KQ-F1	F	Adolescents/adults with persistent uncontrolled asthma despite optimised Step 4 (medium/high-dose ICS–LABA ± MART) therapy	Specialist assessment and eligibility determination for advanced add-on therapy (LAMA, biologic, azithromycin, bronchial thermoplasty)	Continued optimisation without specialist referral	Correct classification of severe/difficult-to-treat asthma; appropriate advanced-therapy eligibility; Specialist-Care/Advanced-Therapy PMB applicability	*High-cost gatekeeping decision for Specialist-Care/Advanced-Therapy tiers*
KQ-F2	F	Patients with confirmed severe asthma and evidence of Type 2 inflammation despite optimised high-dose ICS–LABA therapy	Phenotype-directed biologic therapy	Continued standard therapy (including maintenance oral corticosteroids) without biologic	Exacerbation reduction; oral-corticosteroid sparing; Advanced Therapy PMB applicability and funding eligibility	*Highest per-patient PMB cost impact — biologic therapy funding eligibility*
G — Patient Education and Self-Management						

ID	Domain	Population	Intervention	Comparator	Outcome	Priority basis
KQ-G1	G	All patients with asthma	Structured asthma education and a personalised written asthma action plan, reviewed regularly	No structured education/action plan	Self-management capability; reduced emergency department visits/hospitalisation; Core PMB Care applicability	*Foundational, low-cost, high-impact intervention across all PMB tiers*