Centre for Sustainable Delivery

NHS SCOTLAND

Modernising Patient Pathways Programme

Severe Asthma

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Background

Severe asthma represents around 4% of all asthma, yet contributes to the majority of unscheduled care costs, admissions and overall morbidity. Steroid burden is high in this group of patients, leading to long-term complications of steroid overuse, resulting in very high cost to the NHS. People with severe asthma have poor quality of life, reduced ability to work, carry significant morbidity and have a higher risk of mortality.

'Biologic therapy' (Monoclonal antibodies targeting the severe asthma pathway) is available in Scotland and has been shown in a research and real work environment to dramatically reduce exacerbation frequency in this group of patients (~80% reduction), and reduce steroid burden, admission rates and long-term costs.

Data shows that around 30% of people eligible for biologics are currently receiving them in Scotland as a number of barriers exist:

- Low referral rates from primary care to specialist services
- Variation in provision of severe asthma services across Scotland, and within boards
- Cost and financial governance
- Capacity for follow-up and review
- Respiratory specialist nurse availability
- Complexity of case mix.

The pathway aims:

- To give clear guidance to primary care clinicians regarding timely referral for people with suspected severe asthma
- Triggers for referral to secondary care severe asthma services
- Demonstrate the pathway of care from referral point to initiation of biologics for appropriate patients
- Provide guidance for Multidisciplinary Team (MDT) membership and process

Pathway recommendations

The Centre for Sustainable Delivery (CfSD) Respiratory Specialty Delivery Group (SDG) Asthma Sub Group has produced an updated version of the Severe Asthma Pathway based on the initial version, which was developed by members of the Scottish Severe Asthma Community and Astra Zeneca (in a non-promotional capacity) through the PRECISION Asthma initiative.

This pathway reflects the shared views of specialists of the Severe Asthma Sub Group of the Respiratory SDG. It is intended as guidance, not a strict set of rules, and outlines good practice for identifying, assessing and treating severe asthma.

It was developed by healthcare professionals from both GP and hospital services across different health boards, with input from patients and carers.

While it cannot cover every possible situation, the pathway sets out a patient-centred approach to helping people access severe asthma treatments more quickly, based on realistic, evidence-based and value-focused decision-making.

SMC (Scottish Medicines Consortium) advice is available for the treatments recommended. Where there is deviation from SMC guidance, the deviation is clearly marked, and made clear that the Pathway Development Group support this deviation at this time.

This pathway does not replace SIGN 245 guidance on the diagnosis and management of asthma, rather it supplements the SIGN 245 which does not broach specifically the diagnosis and management of Severe Asthma. Guidance on severe asthma in SIGN 158 is currently under review and due for publication in 2028.

Clinicians remain responsible for how they use this pathway, taking into account local services and the individual needs and preferences of each patient.

Details of the pathway flowchart can be found in the following pages:

The Severe Asthma Pathway for Scotland

Primary Care Management

SIGN245 Asthma Guidance

Refer to BTS/SIGN/NICE guidance for the diagnosis and managment of asthma.

Criteria to identify patients at risk of severe asthma:

•≥6 SABA prescriptions in previous 12 months

Or

•≥2 asthma exacerbations/OCS prescriptions in previous 12 months

Or

•ACQ6 >1.5 (or ACT <20) despite maximum inhaled therapies (ICS,LABA,LAMA)

Y

Optimise current therapy

- Check and address medication adherence, prescription numbers, digital monitoring
- Consider switch to AIR/MART strategy (Refer to SiGN245)
- Check and correct suboptimal inhaler technique
- Check and address modifiable risk factors for severe asthma
- Provide Personal Asthma Action Plan
- Signpost to third sector resources, e.g. Asthma + Lung UK

Review in 8–12 weeks

Is asthma controlled?

N

Y

Maintain therapy and schedule annual review

Direct referral to severe asthma clinic

- Any patient receiving maintenance OCS for asthma (> 3 weeks course)

Or

- ≥3 exacerbations in previous 12 months

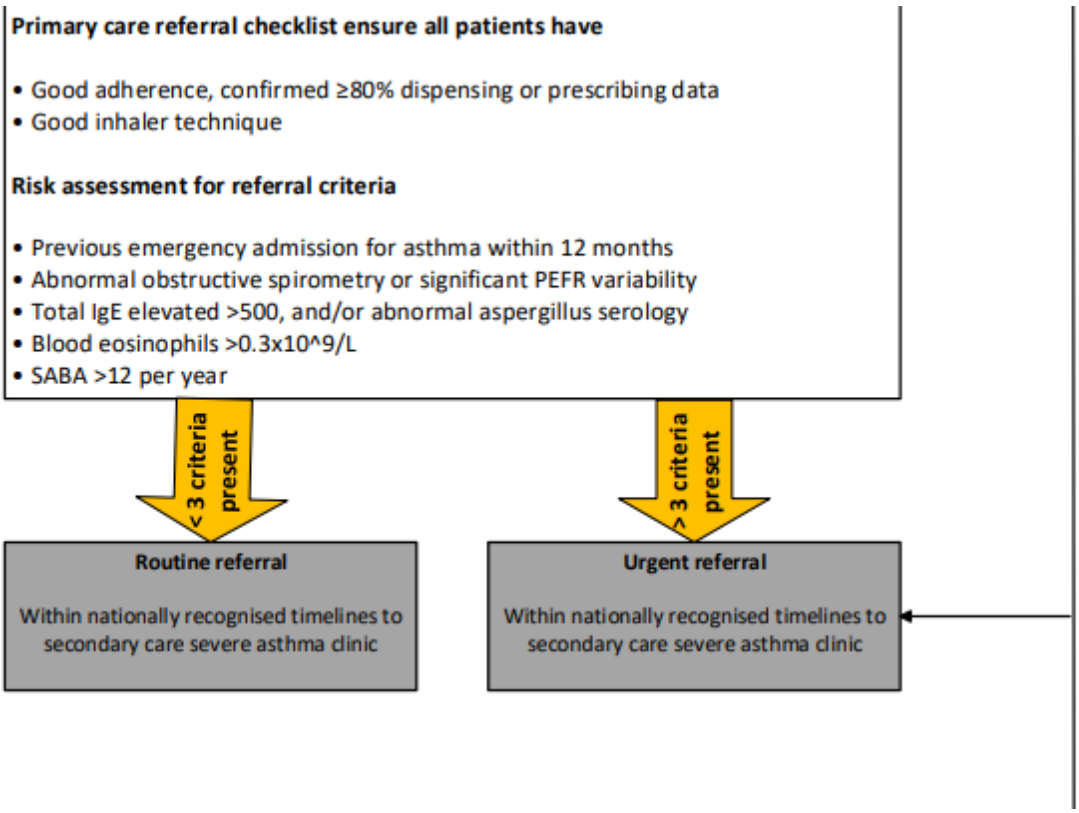
Consider direct referral for any patient receiving moderate dose MART therapy who has had 3 or more exacerbations in any 12 month period who has either

•Eos > 0.3

•FeNO > 30

Modifiable risk factors for severe asthma

- Cigarette smoking
- Inadequate medication
- Poor adherence, confirmed ≤ 80% dispensing or prescribing data
- Poor inhaler technique
- Occupational triggers
- Exposure to allergens or irritants
- Inactivity or sedentary lifestyle
- Obesity
- Psychosocial concerns, anxiety, depression


Primary care referral checklist ensure all patients have
• Good adherence, confirmed ≥80% dispensing or prescribing data
• Good inhaler technique
Risk assessment for referral criteria
• Previous emergency admission for asthma within 12 months
• Abnormal obstructive spirometry or significant PEFR variability
• Total IgE elevated >500, and/or abnormal aspergillus serology
• Blood eosinophils >0.3x10^9/L
• SABA >12 per year
< 3 criteria present
> 3 criteria present
Routine referral
Within nationally recognised timelines to secondary care severe asthma clinic
Urgent referral
Within nationally recognised timelines to secondary care severe asthma clinic

Secondary Care Management Vetting

Refer to National and Local ACRT Guidance

Core tests at vetting

- PFT with reversibility, FeNO
- Bloods:

- FBC; U&E; LFT;

- Total and specific IgE to house dust mite, cat and dog dander, grass and tree pollen and aspergillus

Consider additional tests at vetting

- Bloods: IgM/G/A; functional antibodies; ANCA; ANA
- HRCT
- Sputum culture, Mycobacterial culture
- Pharmacogenomics

Secondary Care Clinic Assessment

Adherence assessment

- Primary care prescribing/dispensing data >80% prescribed dose
- Blood prednisolone and cortisol for those on mOCS
- FeNO suppression test or digital inhaler

Optimise current asthma medication if required as per formulary

- Respiratory nurse specialist assessment of inhaler technique
- Review of asthma action plan and optimise self-management
- Signpost to third sector resources, eg Asthma + Lung UK

Address modifiable factors

- Cigarette smoking; inadequate medication; poor adherence; poor inhaler technique
- Occupational triggers
- Exposure to allergens or irritants
- Inactivity and/or sedentary lifestyle
- Obesity
- Psychosocial issues

Consider alternative and additional diagnoses

CRSwNP; GORD; anxiety and depression; Breathing Pattern Disorder (BrPD); inducible laryngeal obstruction

Consider if referral required

- ENT clinic
- Respiratory Physiotherapy
- Smoking cessation service
- SLT
- GI
- Clinical psychology
- Assess glucocorticoid toxicity risk
- Assess CV risk

Regular MDT

- Identify the key members of the MDT, and local standards
- Consensus decision on suitability for biologic therapy
- Identify patients suitable for clinical trials.

Consider alternative diagnoses

Criteria for biologic therapy

- Optimised therapy
- Adherence check
- TH2 biomarker assessment
- mOCS and/or ≥ 3 exacerbations requiring steroids in 12 months

Consider non-biologic options

- Macrolides
- Manage comorbidity
- Add-on Therapies

Governance and data collection

Collect a comperhensive dataset for all patients discussed at severe asthma MDT, and at review touchpoints. Switch of biologic therapy should be carried out through a comprehensive review by the severe asthma MDT

Biologic assessment tool decisions should be made via severe asthma MDT processes

Refer to SMC recommendations and local formulary guidance

Adopt a Pragmatic, Realistic Medicine and Value Based Health Care Approach To Selection of Biologic Therapy

Biologic choice should be made based on the phenotype of the patient, and likelihood of success and early remission

Local formulary choices should be flexible, to allow as wide a selection as possible to the MDT, in keeping with the most up to date clinical and research expert views

Biomarkers / treatable traits

- Age of onset
- FeNO
- Eosinophils
- Nasal polyposis
- Sensitivity to aeroallergens
- Mucus plugs
- Airway hyperresponsiveness
- Total IgE
- Body weight

Additional considerations

- Realistic medicine; values based health and care
- Patient preference
- Dosing regimen
- Concomitant syndromes such as Atopic dermatitis, EGPA, ABPA, CRSwNP, persistent airflow obstruction
- Background therapy burden
- Refer to adverse events for each biologic
- Combination of asthma biologic therapies is not currently licensed
- Consider previous response to other targeted therapy

Omalizumab; Mepolizumab; Benralizumab; Dupilumab*; Tezepelumab

Can all be considered first line therapy in appropriate patients, following comprehensive phenotypic assessment and MDT discussion.

**Refer to SMC recommendations and local formulary guidance.*

Initiate biologic therapy

- Assess injection technique and provide patient education
- Switch to self-administration after initiation if clinically appropriate
- Incorporate digital technologies for remote monitoring where available and appropriate

Assess response

- Review post initiation of biologic therapy at 3 to 6 months. Review yearly thereafter, or earlier if clinically indicated
- Assess patient reported outcomes using validated asthma questionnaires to assess response ACQ, ACT, mini-AQLQ/full AQLQ
- Assess treatment burden: reduction in OCS rescue courses, hospital admis- sions, OOH/ED attendances, and reduction of maintenance OCS dose
- Refer to guidance on continuation of therapy: 50% reduction in exacerbations or OCS burden

OCS weaning

- Consider mOCS weaning at 1 month post initiation of biologic therapy, review at 3 months
- A structured mOCS weaning protocol should be used routinely E.g. PONENTE protocol
- Formal adrenal function assessment is strongly recommended prior to stopping mOCS, refer to local guidance. E.g.PONENTE protocol

Weaning of asthma therapies – realistic medicine

- Once stable on biologic therapy, and weaned off maintenance OCS – consider reducing other therapies
- Order of weaning of therapies should be based on an assessment of phenotype, initial response to therapies, risks associated with the therapies, reduction in variety of inhaler devices, and patient choice
- Wean high dose ICS to moderate, then low dose ICS
- Patients with severe asthma should remain on regular maintenance ICS doses

Responder status

Good: ≥ 50% reduction in exacerbation or OCS burden

Partial: < 50% reduction in exacerbation or OCS burden with improvement in QoL, reduction in healthcare utilisation

Poor: No evidence of objective or subjective improvements

Good response

- Prioritise mOCS weaning
- Wean other asthma therapies (refer to weaning of asthma therapies-realistic medicine)
- Reduce high dose ICS/LABA to medium dose ICS/LABA

Partial response

- Consider continued treatment trial
- Consider Biologic Switch
- Reassess alternative and additional diagnoses
- Consider re-discussion at Severe Asthma MDT

Poor response

- Assess treatment compliance
- Reassess alternative and additional diagnoses
- Rediscuss at Severe Asthma MDT for consideration of biologic switch
- Stop biologic therapies that are ineffective

ABPA, Allergic bronchopulmonary aspergillosis; ACQ, Asthma Control Questionnaire; ACT, Asthma Control Test; ANA, antinuclear antibody; ANCA, antineutrophil cytoplasmic antibody; AQLQ, Asthma Quality of Life Questionnaire; BLF, British Lung Foundation; BMI, body mass index; CRSwNP, Chronic rhinosinusitis with nasal polyps; CV, cardiovascular: ED, emergency department; EGPA, Eosinophilic granulomatosis with polyangiitis; ENT, ear, nose and throat; Eos, eosinophils; FBC, full blood count; FeNO, fractional exhaled nitric oxide; GI, gastrointestinal; GORD, gastro-oesophageal reflux disease; HRCT, high-resolution computed tomography; ICS, inhaled corticosteroid(s); Ig, immunoglobulin; IL, interleukin; LABA, long-acting ß2-agonist; LAMA, long-acting muscarinic antagonist; LFT, liver function test; mOCS, maintenance oral corticosteroids; MDT, multidisciplinary team; OCS, oral corticosteroid(s); OOH, out of hours; PEFR, peak expiratory flow rate; PFT, pulmonary function test; ppb, parts per billion; QoL, Quality of Life; R, receptor; SABA, short-acting ß2-agonist; SLT, speech and language therapy; SMC, Scottish medicines consortium; TH2, type 2 helper; U&E, urea and electrolytes 1

References and further resources

Asthma Pathway (BTS, NICE, SIGN) [SIGN 244] via RDS

BTS Managing Difficult and Severe Asthma via RDS

If you have any feedback, please contact: gjnh.cfsdpmo@gjnh.scot.nhs.uk

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