# The severe asthma pathway for NHS Highland*

## Primary care management

**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[1-3]

*Or*
- ACQ6 >1.5 (or ACT <20) despite maximum inhaled therapies (ICS,LABA,LAMA)[1,2]

**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 patients with
- Asthma with Eos > 0.8 or FeNO > 50 (if available in primary care)

**Optimise current therapy[1-3]**
- Check and address medication adherence, prescription numbers, digital monitoring
- 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[1-3]**

**Is asthma controlled?**

Y

**Maintain therapy and schedule annual review [1-3]**

**Modifiable risk factors for severe asthma[1-3]**
- 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

N

**Primary care referral checklist† ensure all patients have**
- Good adherence, confirmed ≥80% dispensing or prescribing data[4]
- Good inhaler technique[1-3]

**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 >0.3x10⁹/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 national recognised timelines to secondary care severe asthma clinic

## Secondary care management vetting

**Core tests at vetting[2†]**
- 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[2†]**
- Bloods: IgM/G/A; functional antibodies; ANCA; ANA
- HRCT
- Sputum culture, Mycobacterial culture
- Pharmacogenomics

### Secondary care clinic assessment[2,3†]

**Adherence assessment**
- Primary care prescribing/dispensing data >80% prescribed dose[4]
- 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; disordered breathing pattern; inducible laryngeal obstruction

**Consider if referral required**
- ENT clinic
- Chest physiotherapy
- Smoking cessation service
- SLT
- GI
- Clinical psychology
- Assess glucocorticoid toxicity risk
- Assess CV risk

**Regular MDT[1,3]**
- Consensus decision on suitability for biologic therapy
- Identify patients suitable for clinical trials

**Consider alternative diagnoses**

**Criteria for biologic therapy[3-13]**
- Optimised therapy
- Adherence check
- TH2 biomarker assessment
- mOCS and/or ≥ 3 exacerbations requiring steroids in 12 months

**Consider non-biologic options**
- Macrolides; manage comorbidity

**Governance and data collection**

Collect a comprehensive 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**

**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[1,12,13]
- Combination of asthma biologic therapies is not currently licensed
- Consider previous response to other targeted therapy

**SMC approval criteria[6,8,10,12,14]**
- Anti-TSLP: ≥3 exacerbations and no mOCS or eosinophils ≥150 cells/uL+mOCS
- Anti-IL5r/Anti-IL5: eosinophils ≥150 cells/uL, and either ≥4 prior asthma exacerbations needing systemic corticosteroids in the previous 12 months or treatment with mOCS over the previous 6 months
- Anti-IgE - mOCS + allergic IgE-mediated asthma
- Anti-IL4/13: for the treatment of patients with blood eosinophils ≥150 cells/uL and FeNO ≥25 parts per billion, and ≥4 exacerbations in the preceding year, who have previously received biologic treatment with anti-IgE or anti-IL-5 therapies

**Initiate biologic therapy**
- Assess injection technique
- Switch to self-administration after initiation if clinically appropriate
- Incorporate digital technologies for remote monitoring where available and appropriate[1-3]

**Assess response**
- Review post initiation of biologic therapy at 3 to 6 months. Review yearly thereafter, or earlier if clinically indicated[3]
- Assess patient reported outcomes using validated asthma questionnaires to assess response ACQ, ACT, mini-AQLQ/full AQLQ[3]
- Assess treatment burden: reduction in OCS rescue courses, hospital admissions, OOH/ED attendances, and reduction of maintenance OCS dose
- Refer to guidance on continuation of therapy: 50% reduction in exacerbations[11,13] or OCS burden[13]

**Responder status**

Good: ≥ 50% reduction in exacerbation[11,13] or OCS burden[13]
Partial: < 50% reduction in exacerbation[11,13]
or OCS burden[13] with improvement in QoL, reduction in healthcare utilisation[3]
Poor: No evidence of objective or subjective improvements

**Good response *[3]**
- 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[3]**
- Consider continued treatment trial
- Consider Biologic Switch
- Reassess alternative and additional diagnoses
- Consider re-discussion at Severe Asthma MDT

**Poor response[3]**
- Assess treatment compliance
- Reassess alternative and additional diagnoses
- Rediscuss at Severe Asthma MDT for consideration of biologic switch
- Stop biologic therapies that are ineffective

**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[15]
- Formal adrenal function assessment is strongly recommended prior to stopping mOCS, refer to local guidance. E.g. PONENTE protocol[15]

**Weaning of asthma therapies – realistic medicine[3,16]**
- 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

†Tests to be undertaken as per local/regional pathways or pre-clinic screening agreements, If available, does not exclude from onward referral.
*Please refer to relevant SmPC before prescribing.

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