Evaluation of appropriateness of inhaled corticosteroid (ICS) therapy in COPD and guidance on ICS withdrawal

This guide provides an algorithm to identify people with chronic obstructive pulmonary disease (COPD) who might benefit from ICS treatment and those in whom it may not be appropriate, and an approach to withdrawing ICS in patients in whom it is not needed.

- In symptomatic patients with COPD at low risk of exacerbation, bronchodilation should be the first-line treatment. [GOLD 2017]. In symptomatic patients on monotherapy, treatment can be stepped up to a combination long-acting β2-agonist plus long acting muscarinic antagonist (LABA+ LAMA), and for patients with severe breathlessness (CAT score 10 or MRC grade 2) initial therapy with LABA+LAMA may be considered [GOLD 2017].
- In patients with symptoms (CAT score <10 or MRC grade <2) at high risk of an exacerbation,

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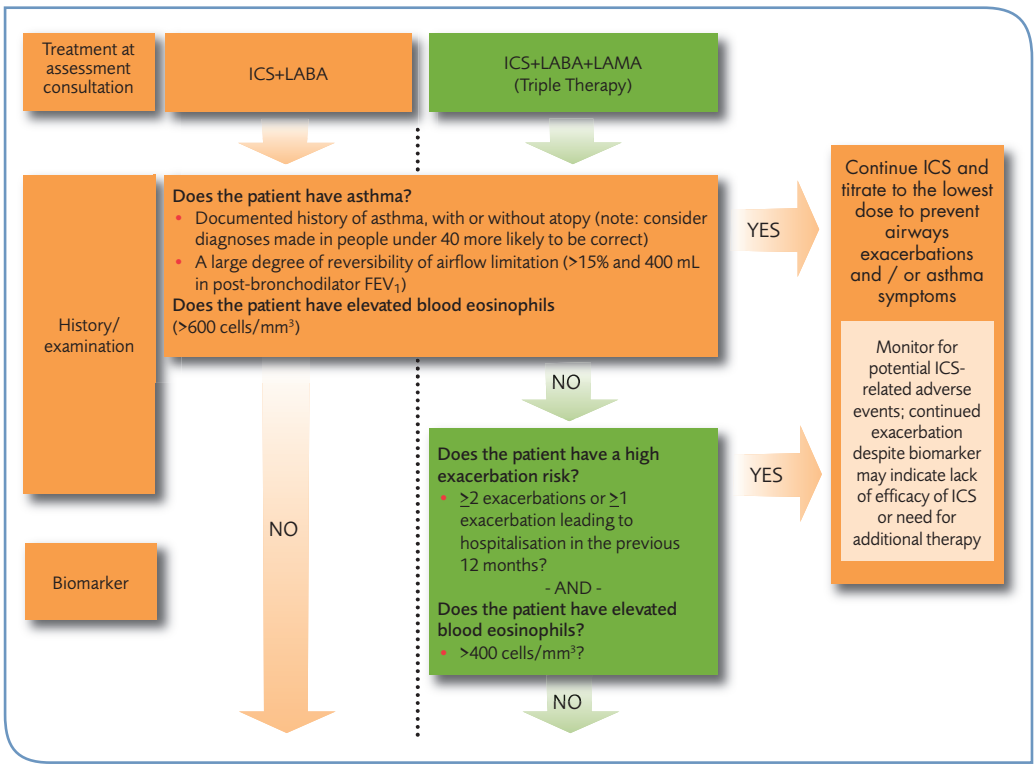

For people with COPD who don't need ICS

Remove ICS or switch to lower-dose ICS in separate inhaler

- Low/Medium-dose* ICS → stop ICS; Switch to LABA/LAMA (optimised bronchodilation)
- High-dose* ICS → switch to lower-dose* ICS in separate inhaler#; In combination with LABA/LAMA (optimised bronchodilation)

4 weeks

Interim call with patient (approx. 2 weeks) to check compliance and ensure stability

Consultation with monitoring clinician including assessment of pulmonary function using spirometry

- If stable or improved: continue with LABA/LAMA (optimised bronchodilation)
- If stable or improved: continue with LABA/LAMA (optimised bronchodilation); stop ICS in separate inhaler

4 weeks

Patient should be encouraged to contact monitoring clinician if any worsening of symptoms or conditions

If stable or improved: continue with LABA/LAMA (optimised bronchodilation)

6 months

Reassess need for ICS use if:
- moderate or severe exacerbations
- airflow limitation worsening (FEV1 decrease ≥100 mL)
- Optional (blood eosinophil count >400)

Follow-up with monitoring clinican for full clinical review

See the patient
- twice yearly during the first year of ICS withdrawal,
- followed by an annual review if the patient's COPD is stable and exacerbation-free

* See next figure # ICS that is not in a combination inhaler is not licensed for treatment of COPD

Note: Whilst the use of LAMA and LAMA+LABA combinations are recommended as options by GOLD for patients at risk of exacerbation, the licensed indications are as maintenance bronchodilator treatments to relieve symptoms in adult patients with COPD.

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the recommended first-line treatment is a LAMA (stepping up to LABA+LAMA if necessary) or a LABA+LAMA. In more symptomatic high risk patients, combination LABA+ LAMA is the preferred first-line treatment, with LAMA or ICS+ LABA given as alternative options [GOLD 2017]. If exacerbations persist on LABA+ LAMA, patients can be stepped up to LABA+ LAMA+ICS (triple therapy).

- Long-term ICS use is associated with a significant risk of pneumonia [Yawn 2013; Suissa 2013; Kew & Seniukovich 2014], and systemic effects [Price 2012]; therefore ICS-containing regimens are not recommended in low-risk patients, and should only be considered for high-risk patients with features of asthma, or as triple therapy if exacerbations persist despite treatment with a LABA+LAMA [GOLD 2017].
- Discontinuing ICS rapidly decreases the risk of serious pneumonia [Suissa 2015].
- Despite years of guidance on the limited role of ICS in COPD [GOLD 2001], there is evidence of inappropriate use of ICS in COPD patients who are at low risk of exacerbation [Vestbo 2014; Price 2014].
- Recent studies have indicated that ICS can be withdrawn in both low- and high-risk patients, provided adequate bronchodilator therapy is in place [Rossi 2014a; Rossi 2014b; Magnussen 2014]. Withdrawal of ICS only increased exacerbation rates in patients with both raised eosinophils and a history of frequent exacerbations [Calverley 2016].

ICS dose switch guidance

Commonly prescribed ICS treatments for COPD and recommended ICS in separate inhaler for change in treatment

Current treatment	Switch to
• Fluticasone/salmeterol - 250/50µg 1 puff twice daily	• LABA/LAMA
• Beclomethasone/formoterol - 100/6µg 2 puffs twice daily	• LABA/LAMA
• Fluticasone/vilanterol - 92/22µg 1 puff once daily	• LABA/LAMA
• Budesonide/formoterol - 400/12µg 1 puff twice daily - 200/6µg 2 puffs twice daily	• LABA/LAMA
• Budesonide/formoterol - 400/12µg 2 puffs twice daily	• LABA/LAMA plus - budesonide 200µg 2 puffs twice daily
• Fluticasone/salmeterol - 500/50µg 1 puff twice daily	• LABA/LAMA plus - fluticasone 250µg 1 puff twice daily

The following fixed ICS/LABA combination brands are licensed in COPD: Seretide Accuhaler, AirFluSal Forspiro, Relvar Ellipta, Symbicort, DuoResp Spiromax, FostairMDI and Foster NEXThaler, Fobumix Easyhaler

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