

Tees CCGs Stopping inhaled corticosteroids in patients with COPD with FEV1 > 50% predicted or Gold group A or B
 Use with Tees CCGs COPD guideline and COPD inhaler guide ([INSERT LINKS](#))

1. Identify all COPD patients on ICS (including triple therapy) with FEV1 > 50% predicted or Gold group A or B

2. Are there ANY of the following?

- History of asthma
- History of COPD/asthma overlap syndrome
- Eosinophil level in last 12 months ≥ 0.3
- Started on ICS in the last 6 months

Yes

4(b). Continue current therapy
 (ICS + appropriate bronchodilation)

If receiving ICS/LABA + LAMA, consider changing to triple inhaler depending on patient preference

Undertake usual annual review as per Tees CCGs COPD guideline and ensure offering of pulmonary rehab

No

3. Has the patient had either of:

- ≥ 2 exacerbations requiring antibiotics +/- oral steroids in the last 12 months
- OR**
- ≥ 1 exacerbation(s) requiring hospital admission in the last 12 months

OR: have they ever previously been classed as a frequent exacerbator based on these criteria?

Yes

KEY

ICS = Inhaled corticosteroid
 LAMA = Long acting muscarinic antagonist
 LABA = Long acting beta agonist

No

4(a). Discuss risk/benefit and if patient agrees:

STOP: ICS/LABA + LAMA
and
START: LAMA/LABA

Discuss:

- Which LAMA/LABA inhaler device the patient would prefer **and** check inhaler technique with the new device
- How to manage breathlessness (offer PR)
- How to manage exacerbations
- Ensure patient has an updated COPD self-management plan.
- Review patient via phone after 3-4 weeks
- Arrange review in **6 months**.

Patient may be reviewed earlier if clinically indicated.

5. At the 6 month review:

If either of:

- ≥ 1 exacerbations requiring antibiotics +/- oral steroids in the last 6 months

OR

- ≥ 1 exacerbations requiring hospital admission in the last 6 months

Consider:

STOP: LABA/LAMA
and

RESTART: ICS/LABA/LAMA
 (ideally as a triple inhaler)

If ongoing breathlessness alone i.e. in the absence of exacerbations, restarting ICS is unlikely to be beneficial.

- Consider other causes
- Offer lifestyle advice – stop smoking, healthy body weight, regular exercise.
- Refer to pulmonary rehabilitation
- Refer to IAPT (including breathlessness clinic).

With thanks to Sunderland CCG and CHS

Background and supporting evidence for the guidance

Pathology

COPD results from pathological changes to the airways and pulmonary vasculature caused by chronic inflammation and repeated injury and repair. This leads to decreased expiratory volume (FEV1) and reduced gas transfer.

Generally, the inflammatory cells and mediators in COPD are different from those in asthma. However, some patients with COPD have inflammatory features that are consistent with asthma and have a mixed inflammatory pattern with increased eosinophils.

The role of inhaled corticosteroids (ICS) in COPD

In COPD, ICS have been shown to increase the time to next exacerbation and slow the decline in quality of life. The effects are greatest in severe disease and frequent exacerbators. There is increasing evidence that those patients with a mixed inflammatory pattern with increased eosinophils also benefit most from ICS.

The benefit of ICS in patients with milder COPD with infrequent or no exacerbations is less clear. These patients should be managed by achieving maximal bronchodilation – with LABA/LAMA supported with pulmonary rehabilitation to improve dynamic lung function and improve quality of life.

However as most patients with COPD have historically been prescribed ICS/LABA + LAMA, some of these patients with milder disease could be managed with out an ICS.

Note: patients with asthma overlap syndrome or a diagnosis of asthma alongside COPD must always be prescribed ICS as it has a role in managing asthma.

Adverse effects of ICS

Common adverse effects are oropharyngeal candidiasis and voice hoarseness. Use of ICS also increases the risk of pneumonia.

Other potential risks are bone density reduction, worsening of diabetes, development of cataracts and adrenal suppression.

Risk/benefit

The risks and benefits of ICS in COPD patients should be considered to inform the decision about whether to continue use.

Patient criteria for stopping ICS and switching to LABA/LAMA:

The guideline aims to exclude patients who benefit from treatment with ICS i.e.

- **severe disease** (box 1)
- **any asthmatic component** or **signs of corticosteroid responsiveness** (box 2)
(Note that there is still debate about threshold for raised eosinophils and this level is based on the threshold used in the COPD guideline)
- **exacerbates frequently** or have been frequent exacerbators prior to initiation of ICS (box 3)

Switching to LABA/LAMA (box 4a):

Stopping treatment with ICS/LABA + LAMA and switching to LABA/LAMA is based on the experience of the WISDOM and FLAME trials which demonstrated no major immediate adverse consequences provided patients were selected appropriately. This guideline supports selection of appropriate patients.

For clinicians unsure about quick withdrawal of ICS – please see PCRS-UK step down algorithm

www.pcrs-uk.org/sites/pcrs-uk.org/files/SteppingDownICS_FINAL4.pdf

Continuing ICS+LABA+LAMA (box 4b):

Patients may have improved concordance with one inhaler rather than ICS/LABA +LAMA.

All patients: support patients with self management, including completion of a self management plan. If starting a new inhaler refer (or get patient to ask) for a community pharmacy new medicines service review so that inhaler technique can be reinforced.

Review of patients who have been switched to LABA/LAMA (box 5) :

If the patient has exacerbated and required admission, antibiotics or oral steroids explore the reason for exacerbating with the patient and make a shared decision about whether to continue on LABA/LAMA or to restart ICS+LABA+LAMA.

Patients who experience breathlessness: consider whether this is a long-standing problem. There is no evidence that ICS improves breathlessness in the absence of other symptoms. Restarting ICS is unlikely to improve breathlessness alone. Discuss other strategies.

Patient information leaflet – stopping inhaled corticosteroids (ICS) in chronic obstructive pulmonary disease (COPD)

What is COPD?

COPD is a disease of the lungs and airways caused by exposure to irritants such as cigarette smoke. Over time, the airways and lungs become inflamed and damaged. This makes it more difficult to breathe and reduces the amount of oxygen that the body absorbs.

Symptoms are wheeze, breathlessness, cough, mucus (phlegm) production and frequent chest infections. From time to time there may be a flare up of the disease (exacerbation) where the symptoms get worse with increased breathlessness and increased phlegm or discoloured phlegm.

What are inhaled corticosteroids?

These are inhalers that work by reducing the inflammation in the airways and lungs.

People with COPD are usually prescribed the corticosteroid in a combination inhaler with another medicine called a long acting beta agonist (LABA).

Examples are – Seretide (containing fluticasone), Symbicort (containing budesonide), Fostair (containing beclometasone.)

What are the side effects of inhaled corticosteroids?

Long –term use of high doses of inhaled corticosteroids can increase the risk of side effects such as: pneumonia, diabetes, reduced bone density and increased risk of fractures, cataracts, sleep disorders, anxiety, depression, thrush in the mouth and sore throat, thinning of the skin (especially in older people.)

Why are my inhaled corticosteroids being stopped?

Inhaled corticosteroids can reduce the frequency and severity of flare-ups of COPD. However they do not improve lung function or stop it from getting worse.

New evidence shows that some people with COPD do not need an inhaled corticosteroid. They are best treated with an inhaler containing a long-acting beta agonist (LABA) and a long-acting muscarinic antagonist (LAMA).

These inhalers reduce wheeze and breathlessness and may reduce the risk of a flare up.

Examples are Ultibro Breezhaler (containing glycopyrronium and indacaterol) and Duaklir Genuair (containing aclidinium and formoterol)

We have reviewed your medical record and decided that you meet the criteria for treatment with the LABA/LAMA combination without an inhaled corticosteroid.

Stopping the inhaled corticosteroid will mean you will no longer be at risk from its side effects.

What does this mean for me?

Your COPD treatment will be changed from a ICS/LABA combined inhaler (e.g. Seretide accuhaler) with a separate LAMA inhaler (e.g. tiotropium handihaler) to a LABA/LAMA combined inhaler.

There is no change to your salbutamol inhaler – you should continue to use this as before.

What happens if I do get a flare-up?

If you do get a flare up with worsening breathlessness, increased phlegm and worsening symptoms, follow the COPD self-management plan from your practice nurse.

If you have more than one flare-up over the next six months you should let your practice know.

If your main problem is breathlessness you should try a pulmonary rehabilitation programme – this will give you strategies to better manage your disease yourself. Contact your GP practice for further details. Restarting the inhaled corticosteroid will not help to relieve breathlessness.