Optimisation of inhalers and inhaled corticosteroid dose for adults with COPD

Step 1: Review current management

- Reassess device technique and adherence
- Risk reduction: advise on smoking cessation (if applicable) and ensure immunisations are up to date
- Optimise function: encourage pulmonary rehab, maximise physical activity, ensure adequate nutrition

Step 2: Evaluate risk-benefit profile of continuing current dose of ICS

- Check patient history, symptoms (e.g. MRC, mMRC, CAT), clinical features and co-morbidities
- Check spirometry results and diagnosis, if asthma is suspected full work up is required
- Check blood eosinophil levels (re-test if no value available in last 2 years)

Does the patient have a diagnosis of asthma or atopy?

YES

Step 3: Continue ICS
Optimise treatment options – follow the asthma treatment guidelines. If clinically stable on triple therapy with separate ICS & LABA & LAMA inhalers, offer to switch to a single fixed dose triple therapy inhaler (ICS+LABA+LAMA) provided the steroid dose is equivalent.[x]

NO

Does the patient have asthmatic features or signs of steroid responsiveness?

- Substantial variation in FEV_1 over time (at least 400ml) or substantial diurnal variation in peak expiratory flow (at least 20%)
- Blood eosinophil count ≥ 100 cells/µL (0.1×10^9/L) with ≥ 2 exacerbations or ≥1 exacerbation requiring hospitalisation per year
- Blood eosinophil count consistently ≥ 300 cells/ µL (0.3×10^9/L)

YES

Optimise treatment options – high dose ICS may not be required (Note: patients with co-existing asthma may need high dose ICS)

Patient on medium dose ICS*	Patient on high dose ICS**
Step 3: Continue ICS If clinically stable on triple therapy with separate ICS & LABA & LAMA inhalers, offer to switch to a single fixed dose triple therapy inhaler (ICS+LABA+LAMA).	**Step 3: If stable consider step down protocol 2** with a view to stepping down to medium dose ICS

NO

Trial ICS stepdown recommended

Patient on low/medium dose ICS*	Patient on high dose ICS**
ICS can be **stopped** immediately	ICS dose must be **tapered/ reduced** slowly
STEP 3: Refer to step down protocol 1 on page 2	**STEP 3: Refer to step down protocol 2 on page 3**

Preferred triple therapy options: ***Trelegy® Ellipta®*** 1 puff OD (DPI); ***Trixeo® Aerosphere®*** 2 puffs BD (pMDI); ***Trimbow®*** (87/5/9) 2 puffs BD (pMDI)

[x] For ICS dose equivalence refer to NICE inhaled corticosteroid doses & SIGN 158 (table 12)

* Low/medium dose ICS include: Fostair® 100/6, 2 puffs BD or 200/6, 1 puff BD; Luforbec® 100/6, 2 puffs BD or 200/6, 1 puff BD DuoResp® Spiromax®160/4.5, 2 puffs BD or 320/9, 1 puff BD; Symbicort® 200/6, 2 puffs BD or 400/12, 1 puff bd; Relvar® Ellipta® 92/22, 1 puff OD; Trelegy® Ellipta®, 1 puff OD; Trimbow® (87/5/9), 2 puffs BD; Trixeo® Aerosphere®, 2 puffs BD

** High dose ICS include: Fostair® 200/6, 2 puffs BD; Luforbec® 200/6, 2 puffs BD; DuoResp® Spiromax® 320/9 2 puffs BD; Symbicort® 400/12, 2 puffs BD; Seretide® accuhaler 500/50, 1 puff BD; Seretide evohaler 250/25, 2 puffs BD; Flutiform® 250/10, 2 puffs BD

Key: ICS- inhaled corticosteroid; **LABA**- long acting beta agonist; **LAMA**- long acting muscarinic antagonist; **OD**-once daily; **BD**-twice daily; **pMDI**- pressurised metered dose inhaler; **DPI**-dry powder inhaler; **SMI**-soft mist inhaler;

- low carbon footprint; - high carbon footprint

Protocol 1: Patient on Low/Medium Dose ICS → STOP ICS

Patient on low/medium dose ICS (as separate ICS, ICS+LABA or ICS+LABA+LAMA inhalers) ICS can be **stopped immediately**

1. Current low/medium dose ICS regimen

Dual ICS+LABA inhaler +/- separate LAMA

ICS+LABA

DPIs
- Fostair NEXThaler 100/6 1 to 2 puffs BD
- Symbicort turbohaler 200/6 2 puffs BD, 400/12 1 puff BD
- DuoResp Spiromax 160/4.5 2 puffs BD, 320/9 1 puff BD
- Seretide Accuhaler 100/50 1 puff BD, 250/50 1 puff BD
- Relvar Ellipta 92/22 1 puff OD

pMDIs
- Fostair or Luforbec 100/6 1 to 2 puffs BD, 200/6 1 puff BD
- Sereflo 125/25 2 puffs BD
- Flutiform 125/5 2 puffs BD, 50/5 2 puffs BD
- Seretide evohaler 125/25 2 puffs BD, 50/25 2 puffs BD
- Sirdupla 125/25 2 puffs BD

+/-

LAMA
- Braltus Zonda DPI (OD)
- Tiogiva DPI (OD)
- Acopair Neumohaler DPI (OD)
- Spiriva Handihaler DPI (OD)
- Seebri Breezhaler DPI (OD)
- Incruse Ellipta DPI (OD)
- Eklira Genuair DPI (BD)
- Spiriva Respimat SMI (OD)

OR

Triple inhaler

ICS+LABA+LAMA
- Trelegy Ellipta DPI 1 puff OD
- Trimbow (87/5/9) MDI 2 puffs BD
- Trixeo Aerosphere MDI 2 puffs BD

2. Step down options

Review inhaler technique and jointly decide on preferred device going forward

Consider:
- Patient's ability to reliably co-ordinate pressing the canister and inhaling for pMDIs & ability to take fast and deep breath in for DPIs (check with a placebo or an inhaler training device if any concerns)
- Preference for once-daily or twice-daily dosing (DPIs & SMIs = OD; pMDIs = BD)
- If the patient wants (and will use) a spacer
- The inhaler carbon footprint (this is significantly higher for pMDIs)

Switch to LABA+LAMA (optimise bronchodilation)

Once daily DPI preferred
Anoro Ellipta
1 puff OD

OR

Twice daily pMDI preferred
Bevespi Aerosphere
2 puffs BD
(encourage spacer use)

OR

Once daily SMI preferred
Spiolto Respimat
2 puffs OD

All patients should have self-management plan and be advised to contact their monitoring clinician if there is any worsening of symptoms or condition.

6 weeks

3. Consultation with monitoring clinician (continue to assess adherence) - Symptom improvement/ clinically stable?

YES

Continue with LABA+LAMA

6 months

NO

If symptoms or condition worsen:
- Consider switch back to previous inhaled therapy regimen
- Consider assessment of pulmonary function using spirometry
- Review blood eosinophil count
- Review need for additional therapy (including non-pharmacological therapies)
- Consider referral to respiratory team for review

Reassess for alternate treatment:
- Acute onset of moderate to severe exacerbations
- Worsening of symptoms
- Blood eosinophil count > 300 cells/μL (0.3×10^9/L)
- Full clinical review required
- Consider triple therapy if clinically indicated

4. Follow-up with monitoring clinician/community team for full clinical review

Review patient at least twice a year during the first year of ICS withdrawal followed by annual reviews if patient's COPD is stable and the patient is 'exacerbation free'
- If patient has ≥2 moderate exacerbations, hospital admission or experiences a deterioration in symptoms, full clinical review required
- If ≥ 2 moderate exacerbations or ≥1 exacerbation requiring hospitalisation within a year consider ICS+LABA+LAMA therapy **OR** if day-to-day symptoms adversely impact quality of life, consider a 3 month trial of triple therapy. Following clinical review, if symptoms improve continue with ICS+LABA+LAMA, if no symptomatic improvement switch back to ICS+LABA for 3 months. If symptoms persist, refer to specialist team.

Protocol 2: Patient on High Dose ICS → Taper/ reduce ICS

Patient on **high dose ICS**, ICS dose must be **tapered/ reduced slowly**

1. Current high dose ICS regimen

Dual ICS+LABA inhaler +/- separate LAMA

ICS+LABA **+/-** **LAMA**

DPIs

- Fostair NEXThaler 200/6 2 puffs BD
- Symbicort turbohaler 400/12 2 puffs BD
- DuoResp Spiromax 320/9 2 puffs BD
- Seretide Accuhaler 500/50 1 puff BD

pMDIs

- Fostair 200/6 2 puffs BD
- Luforbec 200/6 2 puffs BD
- Sereflo 250/25 2 puffs BD
- Seretide evohaler 250/25 2 puffs BD
- Sirdupla 250/25 2 puffs BD
- Flutiform 250/10 2 puffs BD

- Braltus Zonda DPI (OD)
- Tiogiva DPI (OD)
- Acopair Neumohaler DPI (OD)
- Spiriva Handihaler DPI (OD)
- Seebri Breezhaler DPI (OD)
- Incruse Ellipta DPI (OD)
- Eklira Genuair DPI (BD)
- Spiriva Respimat SMI (OD)

2. Initial Step down options

Review inhaler technique and jointly decide on preferred device going forward

Consider:

- Patient's ability to reliably co-ordinate pressing the canister and inhaling for pMDIs & ability to take fast and deep breath in for DPIs (check with a placebo or an inhaler training device if any concerns)
- Preference for once-daily or twice-daily dosing (DPIs & SMIs = OD; pMDIs = BD)
- If the patient wants (and will use) a spacer
- The inhaler carbon footprint (this is significantly higher for pMDIs)

Select the most appropriate medium dose ICS containing regimen below and switch:

Once daily DPI preferred
Switch to:
Trelegy Ellipta
1 puff OD

OR

Twice daily pMDI preferred
Switch to:
Trixeo Aerosphere
2 puffs BD
(encourage spacer use)

OR

Once daily SMI preferred
Spiolto Respimat
2 puffs OD **AND**
Clenil modulite 200mcg
pMDI - 2 puffs BD

6 to 8 weeks

6 to 8 weeks

All patients should have self-management plan and be advised to contact their monitoring clinician if there is any worsening of symptoms or condition.

3. Consultation with monitoring clinician (continue to assess adherence) - Symptom improvement/ clinically stable?

YES

Further ICS stepdown indicated? – see page 1

NO

NO

YES

Switch to LABA+LAMA

Once daily DPI	Twice daily pMDI	Once daily SMI
Switch to:	***Switch to:***	Stop ***Clenil modulite***
Anoro Ellipta	***Bevespi Aerosphere***	Continue ***Spiolto Respimat***
1 puff OD	2 puffs BD (encourage spacer use)	2 puffs OD

8 weeks

4. Consultation with monitoring clinician - Symptom improvement/ clinically stable?

YES

NO

Continue with LABA+LAMA

6 months

5. Follow-up with monitoring clinician/community team for full clinical review

Review patient at least twice a year during the first year of ICS withdrawal followed by annual reviews if patient's COPD is stable and the patient is 'exacerbation free'

- If patient has ≥2 moderate exacerbations, hospital admission or experiences a deterioration in symptoms, full clinical review required
- If ≥ 2 moderate exacerbations or ≥1 exacerbation requiring hospitalisation within a year consider ICS+LABA+LAMA therapy **OR** if day-to-day symptoms adversely impact quality of life, consider a 3 month trial of triple therapy. Following clinical review, if symptoms improve continue with ICS+LABA+LAMA, if no symptomatic improvement switch back to ICS+LABA for 3 months. If symptoms persist, refer to specialist team.

If symptoms or condition worsen:

- Consider switch back to previous inhaled therapy regimen
- Consider assessment of pulmonary function using spirometry
- Review blood eosinophil count
- Review need for additional therapy (including non-pharmacological therapies)
- Consider referral to respiratory team for review

Reassess for alternate treatment:

- Acute onset of moderate to severe exacerbations
- Worsening of symptoms
- Blood eosinophil count > 300 cells/μL (0.3×10^9/L)
- Full clinical review required
- Consider triple therapy if clinically indicated

References & acknowledgements: Primary Care Respiratory Society. Evaluation of appropriateness of ICS Therapy in COPD and Guidance on ICS withdrawal (link); European Respiratory Society. Withdrawal of inhaled corticosteroids in COPD: a European Respiratory Society guideline. European Respiratory Journal Jun 2020, 55 (6) 2000351 (link); Bedfordshire & Luton CCGs. Protocol for the review of Inhaled Corticosteroid (ICS) use in Adults with COPD, Dec 2019; Greater Manchester Medicines Management Group. COPD Treatment Guideline, Nov 2021.

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Superseded version	Inhaled corticosteroid (ICS) Step down guidance for groups A and B COPD patients Inhaled corticosteroid (ICS) in COPD step down algorithms Both HMMC, December 2018