Key points on this medicine

- Relvar Ellipta 92/22 mcg is a once-daily ICS/LABA combination inhaler that is indicated for the symptomatic treatment of adults with COPD (FEV₁ <70% predicted normal)¹
- Taken once daily, Relvar Ellipta has been shown to significantly reduce the rate of moderate or severe exacerbations compared with twice daily ICS/LABA, of which a high proportion was fluticasone propionate/salmeterol²
- Significantly fewer patients make critical errors* with Ellipta compared with other commonly used inhalers after reading the patient information leaflet³
- The 30-day cost of Relvar Ellipta 92/22 mcg is £22.00⁴
- Relvar is generally well tolerated; as with other ICS-containing medicines there is an increased risk of pneumonia in patients with COPD who are treated with Relvar.¹

*Defined as errors that are likely to result in no, or minimal, medication being delivered to the lung.

Guidance recommendations

- NICE Clinical Guideline 101 on Chronic obstructive pulmonary disease in over 16s: diagnosis and management (2010) recommends ICS/LABA combination inhalers as an option for maintenance therapy in people with stable COPD who:³
  - remain breathless or have exacerbations despite using short-acting bronchodilators as required and have a FEV₁ <50% predicted
  - have a FEV₁ ≥50% predicted and remain breathless or have exacerbations despite maintenance therapy with a LABA
  - remain breathless or have exacerbations despite maintenance therapy with a LAMA, irrespective of their FEV₁
- NICE advises that the choice of drug should take into account the person’s symptomatic response and preference as well as the potential of the drug to reduce exacerbations, its side-effects, and its cost.⁵

Evidence for use

- The effectiveness of Relvar in everyday clinical practice has been assessed in a randomised control trial, comparing once-daily Relvar 92/22 mcg with usual care—usual care was a GP/investigator determined COPD maintenance treatment in accordance with usual clinical practice, the intention was to keep the treatment experience as close to normal as possible, patients could receive a LAMA throughout the treatment period in addition to their randomised treatment²
- In the primary comparison, once-daily Relvar 92/22 mcg (n=1135) demonstrated a superior reduction of 8.4% (95% CI 1.1, 15.2, p=0.02) in the rate of moderate or severe exacerbations compared with usual care (n=1134) (1.74 exacerbations per year compared with 1.90 in the usual-care group)—this analysis was based on the primary effectiveness analysis population (ITT patients with ≥1 moderate/severe exacerbation in the year prior to randomisation)²
- Patients in the Relvar group (n=1325) were also 1.5 times more likely to achieve a CAT score improvement ≥2 units from baseline compared with patients in the usual care group (n=1317) (45% versus 36%, p<0.001)²

Once-daily Relvar 92/22 mcg versus twice-daily ICS/LABA

- In the study outlined above, once-daily Relvar 92/22 mcg was also shown to significantly reduce the rate of moderate or severe COPD exacerbations by 8% compared with twice-daily ICS/LABA, of which a high proportion was fluticasone propionate/salmeterol, see Figure 1.²

Figure 1: Mean annual rate of moderate/severe COPD exacerbations in patients receiving Relvar OD (±LAMA) and ICS/LABA BD (± LAMA)²

<table>
<thead>
<tr>
<th>Relvar OD ± LAMA</th>
<th>ICS/LABA BD ± LAMA</th>
</tr>
</thead>
<tbody>
<tr>
<td>1.67</td>
<td>2.03</td>
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</table>

This means that Relvar prevented 1 moderate/severe COPD exacerbation for every 7 patients treated over 12 months compared with twice-daily ICS/LABA (NNT=6.25)²

Budgetary implications

- Relvar Ellipta is the lowest cost ICS/LABA available for patients with COPD⁴
- The 30-day cost of Relvar Ellipta 92/22 mcg is £22.00⁴
- Relvar Ellipta device contains 30 doses.⁴

Drug name

Relvar Ellipta

Licensed indication for COPD

- Relvar Ellipta is indicated for the symptomatic treatment of adults with COPD with a FEV₁ <70% predicted normal (post-bronchodilator) with an exacerbation history, despite regular bronchodilation therapy.¹

Dosage

- Relvar Ellipta 92/22 mcg:⁴
  - one inhalation once daily at the same time each day, either in the morning or in the evening¹
- Relvar 184/22 is not indicated in COPD; there is no additional benefit compared with 92/22 and there is a potential increased risk of adverse reactions.¹

ICS/LABA combination | 30-day cost¹
-----------------------|----------------|
Fostair 100/6 (formoterol fumarate/beclometasone) | £29.32
Relvar Ellipta 92/22 (fluticasone furoate/vilanterol) | £22.00

ICS=inhaled corticosteroid; LABA=long-acting beta₂-agonist

COPD ▼ Ellipta
(fluticasone furoate/vilanterol inhalation powder)
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This formulary decision guide was developed from content supplied by GlaxoSmithKline in a format developed by Guidelines in Practice. It has been reviewed by GlaxoSmithKline, who funded the development of this document.

Prescribing information can be found overleaf.
Relvar Ellipta Prescribing information

[Please consult the full Summary of Product Characteristics (SmPC) before prescribing]

Relvar ▼ Ellipta (fluticasone furoate/vilanterol (as trifenate) inhalation powder)

Formulary decision guide: Relvar ▼ Ellipta (fluticasone furoate/vilanterol inhalation powder)

COPD

Guidelines in practice

Device

• Significantly fewer patients make critical errors* with Ellipta compared with other commonly used inhalers after reading the patient information leaflet:13
  – five times fewer patients made critical errors using Ellipta compared with MDI

• In a study of patients with COPD,6
  – after initial demonstration of how to use the inhaler, >95% of patients with COPD (n=632) used Ellipta correctly at day 1
  – after 6 weeks of treatment, without further verbal instruction or demonstration, >95% of subjects (n=587) were found to still use the Ellipta inhaler correctly
  – when asked to rate the ease of use of the inhaler after 6 weeks
    >95% of patients (n=587) rated it as either very easy or easy to use

• The Ellipta device (DPI) has a carbon footprint 26 times lower than that of the Evohaler device (MDI) (0.75 kg per 30 day treatment compared with 20 kg for the Evohaler).7

Safety profile

• Data from large asthma and COPD phase III clinical trials were used to determine the frequency of adverse reactions associated with Relvar, the safety population comprised a total of 7034 patients with asthma and 6237 patients with COPD.1

• Adverse events:1
  – Very common adverse reactions (≥1/10)—headache and nasopharyngitis
  – Common adverse reactions (≥1/100 to <1/10)—pneumonia, upper respiratory tract infection, bronchitis, influenza, candidiasis of mouth and throat, oropharyngeal pain, sinusitis, pharyngitis, rhinitis, cough, dysphonia, abdominal pain, arthralgia, back pain, fractures, muscle spasms, and pyrexia
  – Other important side-effects (frequency rare [≥1/10,000 to <1/1000])

• Please consult the full Summary of Product Characteristics for further information and guidance on discontinuation of treatment and/ or appropriate patient referral in the event of disease deterioration, paradoxical bronchospasm, cardiovascular effects, hyperglycaemia, systemic steroid effects, visual disturbance, psychological effects, pneumonia, and use in hepatic impairment.1

• In a 12-week study comparing Relvar Ellipta with fluticasone propionate/salmeterol in patients with moderate/severe COPD, the occurrence of on-treatment adverse events and drug-related adverse events was similar between the two study arms.8

For more information on Relvar Ellipta, please refer to the medicines evidence pack, which can be found at: relvar.co.uk/formulary

References


Adverse events should be reported. Reporting forms and information can be found at www.mhra.gov.uk/yellowcard.

Adverse events should also be reported to GlaxoSmithKline on 0800 221 441.