HERTFORDSHIRE AND WEST ESSEX AREA PRESCRIBING COMMITTEE (APC):
Intranasal corticosteroids for allergic rhinitis

Name	What are they	Indication	Date decision last revised	Decision status	NICE guidance
Intranasal corticosteroids	Mometasone 50mcg/dose nasal spray, fluticasone propionate 50mcg/dose (Nasofan®) nasal spray and fluticasone furoate 27.5mcg/dose (Avamys®) nasal spray	Treatment of the symptoms of seasonal allergic or perennial rhinitis	March 2018. Updated June 2019 (mometasone available 'Over The Counter' [OTC])	Final	NICE – no guidance

These recommendations should be used in conjunction with NHSE Policy guidance: *conditions for which over the counter items should not be routinely prescribed in primary care* and HWE ICB OTC medicines guidance and therefore, **any intranasal corticosteroid should only be prescribed where it is inappropriate for a patient to self-care** (e.g. perennial rhinitis, under 18, other exceptions to policy). The below recommendations should only be used when *prescribing* of an intranasal corticosteroid is required. There are a number of intranasal corticosteroids that can be purchased, including beclometasone, budesonide, mometasone and fluticasone propionate. There appears to be no robust evidence that one steroid product is more effective / safer than another in the short-term.

Recommendation following discussion with local specialists:

Recommended choices of intranasal corticosteroids for allergic rhinitis where it is not appropriate for a patient to self-care:

1st line: Mometasone 50micrograms/dose nasal spray – GREEN (RECOMMENDED FOR USE IN PRIMARY AND SECONDARY CARE)

2nd line: Fluticasone propionate 50micrograms/dose nasal spray (prescribed as Nasofan® only) – GREEN (RECOMMENDED FOR USE IN PRIMARY AND SECONDARY CARE)

3rd line: Fluticasone furoate 27.5micrograms/dose nasal spray (Avamys®) – GREEN (RECOMMENDED FOR USE IN PRIMARY AND SECONDARY CARE)

Recommendation

Recommend Avamys® as a treatment option for allergic rhinitis. Remove beclometasone and budesonide for 1st and 2nd line options of mometasone furoate and fluticasone propionate (Nasofan®) respectively.

The above recommendations should only be used when prescribing of an intranasal corticosteroid is required (i.e. self-care is inappropriate). There are a number of intranasal corticosteroids that can be purchased, including beclometasone, budesonide and fluticasone propionate.

Prescribing Rationale

This treatment was reviewed in light of better availability of intranasal corticosteroids, price changes and licensing changes.

Background Information

- The current HMMC decision on intranasal corticosteroids for allergic rhinitis (November 2010) recommends Beclometasone (prescribed as Beconase®) as 1st line treatment, Budesonide (prescribed as Rhinocort Aqua®) as 2nd line and either Mometasone (Nasonex®) OR Fluticasone propionate (Nasofan®) as 3rd line. The decision was based on cost as evidence presented demonstrated no difference in effectiveness or safety of comparable products.
- HMMC reviewed Avamys® in 2014 and decided it was a low priority therapy, with double red status, but may be considered only for patients with an inability to use standard nasal sprays but able to use the Avamys® device
- The Avamys® device contains the active ingredient fluticasone furoate:
  - Fluticasone furoate is a highly selective intranasal steroid available as an aqueous suspension for the treatment of allergic rhinitis. Although structurally related to fluticasone propionate it has different pharmacology.
- Licensed for: Avamys® is indicated in adults, adolescents and children (6 years and over).
- Avamys® is indicated for the treatment of the symptoms of allergic rhinitis.
- Since the last HMMC review in 2014, there has been a review of evidence, cost, licensing and legal category changes as well as the introduction of the Hertfordshire-wide over the counter (OTC) policy (December 2017). Mometasone is licensed for use from 3 years of age; it has significantly decreased in price and was reclassified as an OTC product in July 2017 (OTC license is for over 18 years), and has launched in the UK as an OTC product from February 2019.

Evidence of Clinical Effectiveness

There is no single trial which directly compares the intranasal corticosteroids.

National Guidance: Summary of evidence considered by the Scottish Medicines Consortium (SMC) (2009): Fluticasone furoate is structurally related to fluticasone propionate but has different pharmacology. Efficacy data from 15 randomised double-blind studies in patients with seasonal or perennial allergic rhinitis. The comparative study of fluticasone furoate versus fluticasone propionate in seasonal allergic rhinitis was conducted in Japanese patients in the cedar pollen season. The primary analysis of the trial was a non-inferiority analysis and the European Medicines Agency noted that non-inferiority trials are not possible in allergic rhinitis due to a lack of sensitivity in outcome measures. In perennial allergic rhinitis, the comparative study versus mometasone furoate was primarily a safety study and not designed to detect treatment differences in efficacy outcomes. Fluticasone furoate has been studied at starting doses, but not at the lower maintenance doses. The European Public Assessment Report by the EMEA for this product does not present evidence from any head to head or active comparator studies, suggesting that their assessment of efficacy was concluded on the basis of placebo-controlled trials. They also concluded that treatment effects relating to nasal symptoms were in the range expected with other marketed products for allergic rhinitis and those relating to ocular symptoms were in the range expected for oral antihistamines used in clinical practice.

British Society for Allergy and Clinical Immunology (BSACI) guidelines for the management of allergic and non-allergic rhinitis (2017). Systemic absorption negligible with mometasone furoate, fluticasone furoate and fluticasone propionate and these preparations are favoured for children. Systemic absorption is modest for the remainder, and high for beclometasone which should be used short-term only.

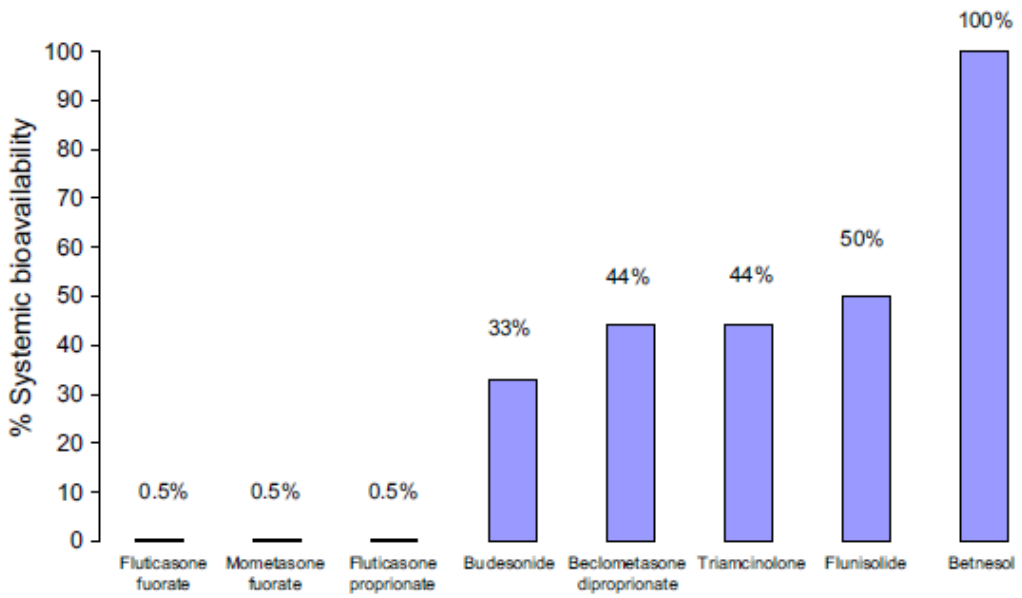

FIGURE 3 Bioavailability of intranasal corticosteroids. The more recent molecules have little systemic uptake and are suitable for use in children and for long-term therapy (Grade A evidence)

As patients over 18 years of age with seasonal allergic rhinitis will be expected to purchase their intranasal corticosteroid for seasonal rhinitis, this evidence is important when choosing clinically appropriate nasal sprays for children and for long-term use.

The current HMMC guidance recommends beclometasone first line which has been shown to have significant systemic absorption. Proposed revised recommendations place mometasone and fluticasone (both furoate and propionate) as preferred choices and these carry lower systemic absorption.

- **Outcome from studies (note those supplied only compared fluticasone furoate to placebo):**
  Efficacy measurements – Total Nasal Symptom Severity (TNSS) and Total Ocular Symptom Severity (TOSS) are recognised scoring systems used in other allergic rhinitis trials, although subjective.

  Reduction in nasal and ocular scores was statistically significantly greater with fluticasone furoate compared to placebo in patients over 12 years old. The results were more variable and not always statistically significant in patients less than 12 years old.

  The difference in effect on quality of life as measured on the Rhinoconjunctivitis Quality of Life Questionnaire (RQLQ) score was clinically significant for patients over 12 years old when compared to placebo.

  The Scottish Medicines Consortium (SMC) (2009) concluded treatment effects relating to nasal symptoms were in the range expected with other marketed products for allergic rhinitis and those relating to ocular symptoms were in the range expected for oral antihistamines used in clinical practice.

Device
The Avamys® delivery device may be easier to use and generally favourable over other intranasal corticosteroids.

Cost of treatment and Cost Effectiveness

- The cost of fluticasone furoate is the same as the previous evaluation in 2014 (£6.44/pack).
- The cost of mometasone furoate has significantly decreased and is less than the current first line choice. There is the potential for cost avoidance by initiating patients on mometasone 50mcg/dose nasal spray, and reviewing patients on more expensive products and switching to mometasone (note any switches would involve a drug, dose and device change).

No cost-effectiveness analysis available.

The needs of the population

- There are a range of products already available for this indication, some of which are cheaper to purchase over the counter for less than the prescription charge. There may however be patients who would benefit from the ease of the delivery system of fluticasone furoate.
- Since December 2017, the Hertfordshire-wide OTC policy expects people to purchase intranasal corticosteroids to treat seasonal allergic rhinitis, therefore, this guidance is only applicable where purchase is not possible i.e. perennial rhinitis and people under 18 years old.

The needs of the community

- If Avamys® is used instead of, or replaced cheaper alternatives, or alternatives available OTC, then this would create a cost pressure which may have an impact on the local health economy.
- If used as an alternative to generic fluticasone propionate there would be a potential cost saving as prescribing data indicates 32% of fluticasone propionate prescriptions are not being prescribed as Nasofan® (Nasofan® and Avamys® are the same price, but generic fluticasone propionate is more expensive).
- Avamys® is not currently available OTC which does not promote the self-care agenda.

Policy Drivers

- OTC policy (December 2017): Whilst beclometasone, budesonide and fluticasone propionate are available over the counter for self-care, these products can only be bought within licensing. Patients under 18 years will require an NHS prescription as well as patients with perennial rhinitis. By Avamys® being a third line option, all patients should demonstrate they have trialled the other options whether prescribed or purchased. Specialists recommending Avamys® should provide rationale for the choice of product, and have exhausted other options or deemed them inappropriate.
- National Institute for Health and Care Excellence (NICE): no current guidelines or technology appraisals on allergic rhinitis
- Scottish Medicines Consortium (2009): Recommended that fluticasone furoate is accepted for use in Scotland and the evidence to support its efficacy comes from a number of comparator- and placebo-controlled studies in adults and children. They also cautioned prescribers to be aware that the recommended doses of fluticasone furoate are not equivalent, on a microgram per microgram basis to other fluticasone nasal sprays available, and that other intranasal steroids are available at a lower cost.
- All Wales Medicines Strategy Group (AWMSG): has not been reviewed.
- Local formulary status: Luton and Dunstable - fluticasone furoate and fluticasone propionate and both non-formulary. Royal Free – Avamys® is on formulary.

Equity
No impact anticipated.

Implementability
No issues identified.

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Version	3.0 Harmonisation of Hertfordshire Medicines Management Committee (HMMC) guidance and West Essex Medicines Optimisation Programme Board (WEMOPB) guidance updates include: • Rebadging with HWE ICB and removal of ENHCCG and HVCCG headers

	• Review date removed and replaced with standard statement.
Developed by	East and North Herts CCG and NHS Herts Valleys CCG PMOT
Approved by	HMMC
Date approved/updated	March 2018, updated June 2019
Review date:	The recommendation is based upon the evidence available at the time of publication. This recommendation will be reviewed upon request in the light of new evidence becoming available.
Superseded version	2.0