South East London Area Prescribing Committee
Formulary recommendation

Reference	**067**
Intervention:	**Azelastine hydrochloride and fluticasone propionate combination nasal spray (Dymista®) for the treatment of moderate to severe seasonal and perennial allergic rhinitis in adults and children 12 years and older** (Dymista is a nasal spray containing a combination of an antihistamine [to reduce allergy symptoms] and a corticosteroid [to reduce inflammation]).
Date of Decision:	**May 2017**
Date of Issue:	**June 2017**
Recommendation	**GREEN – can be prescribed within agreed criteria for use in primary or secondary care**
Further Information:	• Following a re-submission to the SEL APC, azelastine hydrochloride and fluticasone propionate combination nasal spray (Dymista®) is accepted for use within South East London for the management of moderate to severe seasonal and perennial allergic rhinitis. In line with the SEL Allergic Rhinitis pathway. Dymista is a **last line option** in primary care before referral to specialist allergy services is considered. • In line with the allergic rhinitis pathway, the following treatment steps should be trialled before Dymista is considered: – Allergen avoidance – Regular non-sedating anthistamines – Regular nasal corticosteroid spray – Combination of oral antihistamine and nasal corticosteroid – The next step if the above fail would be a combination of oral antihistamine, nasal corticosteroid and nasal antihistamine. [Dymista may be considered at this point as a single device to deliver nasal corticosteroid and nasal antihistamine.] • This approval covers use in adults and children aged 12 years or over. • This recommendation replaces SEL APC recommendation 008 for Dymista (March 2014, grey recommendation). • Dymista was first reviewed by the SEL APC in February 2014. Dymista was not recommended at the time as the Committee felt that it offered no advantage over current treatment and was not as cost-effective as other options. • This re-submission provided improved detail on the place in therapy of Dymista. Additionally, further evidence published since the original formulary submission was considered along with the lower acquisition cost of the product. **Practical issues** (refer also to SPC and patient information leaflet for more detailed information): • The dose for adults and children aged 12 years and over is one actuation of the spray in each nostril twice daily (morning and evening). • One actuation (0.14 g) of the spray delivers 137 micrograms azelastine hydrochloride (= 125 micrograms azelastine) and 50 micrograms fluticasone propionate. Dymista is **not recommended** for use in children below 12 years of age as safety and efficacy has not been established in this age group. Use in this age group would be unlicensed and is not covered by this recommendation and the Allergic Rhinitis pathway • The duration of treatment should correspond to the period of allergenic exposure. • If Dymista has not been used for more than 7 days it must be re-primed once by pressing down and releasing the pump.

Shared Care/Transfer of care document required:	N/A
Cost Impact for agreed patient group	• Addition of Dymista to the formulary is anticipated to have negligible additional costs. The costs of treatment with alternative agents would be displaced. There may also be an opportunity for savings from reduced referrals to specialist allergy clinics as the Allergic Rhinitis pathway supports more management in primary care.
Usage Monitoring & Impact Assessment	**Trusts:** Monitor usage and report back to APC when requested. Audit to ensure use in line with this recommendation and local pathway. **CCGs:** Monitor primary care prescribing data. Audit to ensure use in line with this recommendation and local pathway.
Evidence reviewed	**References (from evidence evaluation):** 1. Scadding GK et al. BSACI guidelines for the management of allergic and non-allergic rhinitis. Clin Exp Allergy 2008; 38: 19-42. 2. An update on the management of hay fever in adults. DTB 2013; 51: 30-3. 3. Carr W et al. Novel intranasal therapy of azelastine with fluticasone for the treatment of allergic rhinitis. Allergy Clin Immunol 2012; 129: 1282-9. 4. Azelastine and flutcasone nasal spray – any advantage? DTB 2014; 52: 21-3 5. Klimek L, Bacharyt C, Moesges R et al. Effectiveness of MP29-02 for the treatment of allergic rhinitis in real life: results from a non-internventional study. Allergy and asthma proceedings 2015 36 p40-47 6. Summary of product Characteristics, Dymista. Available online at: http://www.medicines.org.uk/emc/medicine/27579 (accessed 04/01/2017) 7. Drug Tariff, January 2017 8. Scottish Medicines Consortium, December 2013 – Dymista: 921/13, Available online at: https://www.scottishmedicines.org.uk/SMC_Advice/Advice/921_13_azelastine_hydrochloride_plus_fluticasone_propionate_Dymista (accessed 04/01/2017) 9. Scottish Medicines Consortium, October 2014 – Dymista: 921/13. Available online at: https://www.scottishmedicines.org.uk/SMC_Advice/Advice/921_13_azelastine_hydrochloride_plus_fluticasone_propionate_Dymista/azelastine_hydrochloride_fluticasone_propionate_Dymista_resubmission (accessed 04/01/2017)

NOTES:

a) Area Prescribing Committee recommendations and minutes are available publically on member CCG websites.

b) This Area Prescribing Committee recommendation has been made on the cost effectiveness, patient outcome and safety data available at the time. The recommendation will be subject to review if new data becomes available, costs are higher than expected or new NICE guidelines or technology appraisals are issued.

c) **Not to be used for commercial or marketing purposes. Strictly for use within the NHS.**