South East London Integrated Medicines Optimisation 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, updated June 2024 In line with the publication of SEL Acute Provider Collaborative's Ear, Nose and Throat interface guidelines**
Date of Issue:	**June 2017, Re-issued July 2024**
Recommendation	**GREEN – can be prescribed within agreed criteria for use in primary or secondary care**
Further Information:	• Following a re-submission to the Committee and in line with its licenced use*, 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 South East London Acute Provider Collaborative's (SEL APC) Ear, Nose and Throat (ENT) interface guidelines, Dymista™ can be considered as a **last line option** at the same point in therapy as Ryaltris™ in primary care, before referral to specialist allergy services is considered. Note: There are two separate APC guidelines for ENT conditions – one for adults and one for children. • Formulary recommendation 150 details the use of Ryaltris™ within SEL. • Please refer to the allergic rhinitis section within the SEL APC ENT interface guidelines for information on the treatment steps that should be trialled before Dymista™ is considered. Treatment options are based on the severity of the allergic rhinitis and specific treatment options are noted within the guidelines. • Prescribers should educate patients on proper application technique, potential side effects and precautions of use of Dymista™. Additionally, a clear treatment plan should be established for ongoing use in the community. • 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 summary of product characteristics 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 SEL APC **ENT interface guidelines** for children and young people. • 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. *Dymista™ is licenced for adults and adolescents 12 years of age and older for the treatment of moderate to severe nasal symptoms associated with seasonal and perennial allergic rhinitis.
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 SEL APC **ENT interface guidelines** supports more management in primary care.
Usage Monitoring & Impact Assessment	**Acute Trusts:** Monitor and audit usage of Dymista™ and report back to the Committee (against this recommendation) upon request of the Committee.
	SEL Borough Medicines Optimisation Teams: • Monitor primary care prescribing data. • Exception reports from GPs if inappropriate prescribing requests are made to primary care.
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 fluticasone 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-interventional 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) SEL IMOC recommendations and minutes are available publicly via the website.
b) This SEL IMOC 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.**