South East London Integrated Medicines Optimisation Committee
(SEL IMOC, formerly the SEL Area Prescribing Committee)
Formulary recommendation

Reference	**117**
Intervention:	**Budesonide 3mg gastro-resistant capsules (Budenofalk® 3mg) for the management of autoimmune hepatitis in adults**
Date of Decision:	**October 2020**
Date of Issue:	**November 2020**
Recommendation:	**Amber 2 – specialist initiation and prescribing for 6 months. GP may be requested to prescribe after 6 months.**
Further Information	· Budesonide 3mg gastro-resistant capsules (Budenofalk® 3mg) are accepted for use in SEL as a 2nd line corticosteroid option for the management of autoimmune hepatitis* in non-cirrhotic adult patients. · The use of budesonide is restricted as a **2nd line corticosteroid option** in cases where use of prednisolone is associated with severe (actual or anticipated) steroid-related side effects such as psychosis, poorly controlled diabetes or severe osteoporosis. · With respect to osteoporosis, measures to manage osteoporosis should be implemented before moving to budesonide, including routine prescription of calcium and vitamin D and selective use of bisphosphonate therapy. · The specialist hospital team will prescribe and supply budesonide for the first 6 months of treatment and after this time, if the patient needs to continue treatment, the GP may be requested to prescribe. · The starting dose of budesonide for induction of remission is 3mg three times a day. After achievement of remission the recommended daily dose is 3mg twice a day. · There are limited data on the long-term use of budesonide in this setting although local experts have suggested that only 10-20% of patients will require longer term treatment. The summary of product characteristics (SPC) for budesonide 3mg capsules notes that treatment for maintenance of remission in autoimmune hepatitis should be continued at least for 24 months. It might be terminated only if biochemical remission is constantly maintained and if no signs of inflammation are present in a liver biopsy. · Once stable, patients will be reviewed at 6 monthly intervals by the specialist team. · Treatment should not be stopped abruptly, but withdrawn gradually (tapering doses). Gradual dose reduction over 2 weeks is recommended. The decision to discontinue treatment will be taken by the specialist team. *Budesonide 3mg gastro-resistant capsules (Budenofalk® 3mg) are licensed for the treatment of autoimmune hepatitis.
Shared Care/ Transfer of care required:	N/A
Cost Impact for agreed patient group	· If the prevalence of AIH is 1 in 10,000, then in SE London 190 patients would be expected to have this condition. Assuming that 50% of these presented to clinic for treatment, and 20% of those could not tolerate prednisolone, an estimated 19 patients per annum might be eligible for treatment with budesonide 3mg capsules in SE London. · The additional cost of using budesonide 3mg capsules vs. prednisolone at maintenance dose (maximum daily dose 9mg vs. 10mg respectively) is just under £800 per patient per year. · The estimated additional cost for SEL will therefore be ~£15,000 per year (or ~£800 per 100,000 population). · The additional cost may be lower than estimated above as the patient number estimates provided by local experts are lower (10 patients anticipated for SEL).

Usage Monitoring & Impact Assessment	**Trusts:** · Monitor use and submit usage data and audit reports (against this recommendation) upon request to the SEL IMOC.
	SEL CCG Borough Medicines Teams: · Monitor EPACT 2 data · Exception reports from GPs if inappropriate prescribing requests are made to primary care.
Evidence reviewed	**References (from evidence evaluation)** 1. Gleeson D, Heneghan M. British Society of Gastroenterology (BSG) guidelines for the management of autoimmune hepatitis. Gut 2011 60 p1611-1629. 2. EASL Clinical Practice Guidelines: Autoimmune hepatitis. Journal of Hepatology 2015 63 p971-1004. 3. Budesonide 3mg gastro-resistant capsules (Budenofalk) SMC 1043/15. 4. Budenofalk. Summary of Product Characterisitics. Available online at: https://www.medicines.org.uk/emc/product/138/smpc (accessed 01/11/2019). 5. Manns M, Woynarowski M, Kriesel W et al. Budesonide induces remission more effectively than prednisolone in a controlled trial of patients with autoimmune hepatitis. Gatroenterology 2010 139 p1198-1206. 6. Peiseler M, Liebscher T, Sebode M et al. Efficacy and limitation of budesonide as a second line treatment for patients with sutoimmune hepatitis. Clinical Gastroenterology and Hepatology 2017 doi: 10.1016/j.cgh.2916.12.040. 7. Wiegand J, Schueler A, Kanzler S et al. Budesonide in previously untreated autoimmune hepatitis. Liver International 2005 25 p927-934.

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