South East London Area Prescribing Committee
Formulary recommendation

Reference	**103**
Intervention:	**Mycophenolate sodium (mycophenolic acid) 360mg tablets for autoimmune rheumatic and dermatological conditions in patients unable to tolerate mycophenolate mofetil** (Mycophenolate sodium is an immunosuppressant)
Date of Decision	**August 2019**
Date of Issue:	**September 2019**
Recommendation:	**AMBER 3 – Initiation and minimum 3 months' prescribing and supply by the hospital team**
Further Information	• Mycophenolate mofetil is the standard salt of mycophenolate used as a treatment option (off-label) for autoimmune connective tissue disorders in line with the SEL Joint Medicines Formulary (see list of indications below). • Mycophenolate sodium (mycophenolic acid) in the 360mg enteric coated tablet formulation is supported for use in South East London as 2nd line to mycophenolate mofetil where the following criteria are met: - There is intolerance to mycophenolate mofetil due to gastrointestinal adverse effects such as nausea, vomiting, abdominal pain, diarrhoea, dyspepsia and constipation. **AND** - A reduction in the dose of mycophenolate mofetil has been trialled to mitigate the adverse effects but is unsuccessful. **AND** - Alternative immunosuppressant treatment options have been considered but are not suitable for the patient and the next step would otherwise be treatment with a biologic agent. • Mycophenolate sodium is not licensed for use in this setting. Informed consent should be gained from the patient before treatment is started. • The indications covered by this recommendation are in line with the indications for mycophenolate mofetil, as per the SEL Joint Medicines Formulary: - Severe immunobullous disease - Severe atopic dermatitis - Severe psoriasis - Systemic lupus erythematosus and vasculitis (SLE) - Chronic urticaria - Behcet's disease - Dermatomyositis - Granulomatosis with polyangitis - Scleroderma - Takayasu's arteritis
Shared Care/ Transfer of care required:	Yes – refer to non-biological immunomodulator medicines shared care guidance
Cost Impact for agreed patient group	• The local acute trusts estimate that approximately 40 people might be suitable for treatment with mycophenolate sodium per year in SEL. • For Myfortic® and/or Ceptava®, this equates to a drug treatment cost per patient being in the range of £1,152 to £3,456 per annum (depending on dosage), which is a cost per annum of £46,080 to £138,240 for SE London. • As mycophenolate sodium is now generic, further price reductions are anticipated as more generic versions enter the market. • Inclusion of mycophenolate sodium may also delay the need for a biologic agent.
Usage Monitoring & Impact Assessment	**Acute Trusts:** • Monitor use and report back to APC when required. • Audit use upon request to ensure use is in line with this recommendation.

	CCGs: • Monitor Epact 2 data. • Monitor exception reports from GPs if inappropriate prescribing requests are made to primary care.
Evidence reviewed	**References (from evidence evaluation)** 1. Summary of Product Characteristics, MYFORTIC gastro-resistant tablets (last Updated on eMC 31-Oct-2017) Novartis Pharmaceuticals UK Ltd. Accessed here on 04/03/19 2. M Salvadori et al, Enteric Coated MPS is Therapeutically Equivalent to Mycophenolate Mofetil in de novo Renal Transplant Patients, Am J Clin Transplant 2003;4: 231-236 3. M Salvadori et al, Long-term administration of enteric-coated mycophenolate sodium is safe in kidney transplant patients, Clin Nephrol 2006, 66(2): 112-119 4. K Budde et al, Enteric-coated mycophenolate sodium: safe conversion from mycophenolate mofetil in maintenance renal transplant recipients. Transplant Proc 2004 Mar; 36(2 Suppl):524S-527S. 5. K Budde et al, Long-term safety and efficacy after conversion of maintenance renal transplant recipients from mycophenolate mofetil (MMF) to enteric-coated mycophenolate sodium Clin Nephrol 2006; 66 (2): 103. 6. A Johnston et al, Bioequivalence of enteric-coated mycophenolate sodium and mycophenolate mofetil: a meta-analysis of three studies in stable renal transplant patients. Transplantion 2006; 82(11):1413. 7. South East London Joint Medicines Formulary. Accessed here. Last accessed 04/03/19. 8. R Jones et al, Randomized trial of enteric-coated mycophenolate sodium versus mycophenolate mofetil in multi-system autoimmune disease. Clin Kidney J 2014, Dec;7(6):562-8 9. Martindale: The complete drug reference, Mycophenolate (latest modification: 04-Jul-2017). Accessed via medicinescomplete.com on 27/02/19 10. P Dalal et al, Mycophenolate mofetil: safety and efficacy in the prophylaxis of acute kidney transplantation rejection, Ther Clin Risk Manag 2009; 5: 139–149. 11. NICE, Systemic lupus erythematosus: oral mycophenolate. Evidence summary [ESUOM36]. Published date: November 2014 12. C Gordon et al, The British Society for Rheumatology guideline for the management of systemic lupus erythematosus in adults, October 2017, Rheumatology, kex28 13. E Ntatsaki et al, BSR and BHPR guideline for the management of adults with ANCA-associated vasculitis, Rheumatology 2014, 53(12): 2306–2309V. 14. NICE, Dupilumab for treating moderate to severe atopic dermatitis. Technology appraisal guidance [TA534]. Published date: 01 August 2018. 15. NICE, Psoriasis: assessment and management. Clinical guideline [CG153]. Published date: October 2012 16. Harman KE et al. British Association of Dermatologists' guidelines for the management of pemphigus vulgaris (2017). British Journal of Dermatology; 177: pages 1170-1201. 17. Evelina Paediatric Formulary, Paediatric Formulary, Last Published on Friday, November 20, 2015 9:16:26 AM 18. J Langone et al, Enteric-Coated Mycophenolate Sodium Versus Mycophenolate Mofetil in Renal Transplant Recipients Experiencing Gastrointestinal Intolerance: A Multicenter, Double-Blind, Randomized Study. Transplantation 2011, 91 (4) 19. P Bolin et al, Improvement in 3-Month Patient-Reported Gastrointestinal Symptoms After Conversion From Mycophenolate Mofetil to Enteric-Coated Mycophenolate Sodium in Renal Transplant Patients. Transplantation 2007, 84 (11) 20. Chan L et al, Patient-Reported Gastrointestinal Symptom Burden and Health-Related Quality of Life following Conversion from Mycophenolate Mofetil to Enteric-Coated Mycophenolate Sodium (PROGIS). Transplantation 2006, 81 (9) 21. Erosive enterocolitis in mycophenolate mofetil-treated renal-transplant recipients with persistent afebrile diarrhea. Maes BD, Dalle I, Geboes K, Oellerich M, Armstrong VW, Evenepoel P, Geypens B, Kuypers D, Shipkova M, Geboes K, Vanrenterghem YF Transplantation. 2003; 75(5):665. 22. Mycophenolate mofetil dose reductions and discontinuations after gastrointestinal complications are associated with renal transplant graft failure. Bunnapradist S, Lentine KL, Burroughs TE, Pinsky BW, Hardinger KL, Brennan DC, Schnitzler MA. Transplantation. 2006; 82(1):102. 23. Drug tariff, Accessed via http://www.drugtariff.nhsbsa.nhs.uk/ on 05/03/19 24. British National Formulary, Accessed here on 05/03/19

NOTES:

a) Area Prescribing Committee recommendations and minutes are available publicly via the APC website.

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.