South East London Integrated Medicines Optimisation Committee
Formulary recommendation

Reference	**161**
Intervention:	**Fidaxomicin 200mg film coated tablets and 40mg/ml granules for oral suspension for the treatment of Clostridium difficile (*C. diff*) associated diarrhoea in children under 18 years of age** (Fidaxomicin is a macrocyclic antibiotic with narrow spectrum bactericidal activity)
Date of Decision	**March 2025**
Date of Issue:	**April 2025**
Recommendation:	**RED – suitable for prescribing and supply by the hospital only**
Further Information	• Fidaxomicin is accepted for use in South East London for the treatment of Clostridium difficile associated diarrhoea (CDAD) in children from birth to under 18 years of age • In line with the UK Paediatric Antimicrobial Stewardship (UKPAS) network guidance, the use of fidaxomicin in this setting is approved within the following criteria: - Oral vancomycin is the **first line** treatment for CDAD - Fidaxomicin is a **second line** treatment option following treatment failure with first line oral vancomycin (first cases of C.*diff* infection) - Fidaxomicin may be considered as **first line** for relapsed CDAD within 12 weeks of the 1st episode that has previously been treated with oral vancomycin • Use of fidaxomicin is restricted to the advice of the paediatric microbiology team. All cases of C.*diff* should be reviewed by the paediatric microbiology team prior to initiation of fidaxomicin as treatment is not required for all cases of CDAD. • Fidaxomicin 200mg film-coated tablets and fidaxomicin 40 mg/ml granules for oral suspension are licensed for the treatment of CDAD in this patient cohort. • Treatment with fidaxomicin for CDAD is recommended for 10 days and dosing is in line with the dosing recommendations provided in the BNF for Children • For patients with a body weight less than 12.5kg, fidaxomicin 40mg/ml granules for oral suspension should be prescribed, see the Summary of Product Characteristics for further information. • Fidaxomicin 40 mg/ml granules for oral suspension has specific dose administration instructions and once reconstituted. Appropriate counselling and adequate supply is recommended. • The full treatment supply will be provided by the initiating hospital.
Shared Care/ Transfer of care required:	N/A
Cost Impact for agreed patient group	• It is estimated there will be approximately 2 – 3 patients per annum at each SEL Trust who may be eligible for treatment with fidaxomicin in this setting each year. Approximately 1 - 2 of these patients will be from SEL. • A 10-day course of treatment with fidaxomicin tablets or oral solution including VAT is ~ £1,620, if used in approximately 5 patients per annum in SEL this equates to ~£8,100 per annum (~ £405 per 100,000 population).
Usage Monitoring & Impact Assessment	**Acute Trusts:** • Monitor and audit usage of fidaxomicin and report back to the SEL antimicrobial stewardship network and the Committee upon request.
	SEL Borough Medicines Teams: • Monitor exception reports from GPs if inappropriate prescribing requests are made to primary care

Evidence reviewed	References (from evidence review)
	1. Dificlir – EPAR for licence extension for use in paediatrics. Available online here [Accessed 30/12/2024] 2. NG199: Clostridioides difficile infection: antimicrobial prescribing. National Institute for Health and Care Excellence. Available online here [Accessed 30/12/2024] 3. Advice on antimicrobial management of Clostridioides difficile (C.diff) Infection (CDI) in children. Scottish Antimicrobial Prescribing Group (SAPG) June 2024. Available here [Accessed 30/12/2024] 4. Antimicrobial Paediatric Guide UK-PAS 2024. Available online here [Accessed 30/12/2024] 5. Fidaxomicin 40 mg/ml granules for oral suspension, Summary of Product Characteristics. Available online here [Accessed 30/12/2024] 6. Wolf J, Kalocsai K, Fortuny C et al. Safety and Efficacy of Fidaxomicin and Vancomycin in Children and Adolescents with Clostridioides (Clostridium) difficile Infection: A Phase 3, Multicenter, Randomized, Single-blind Clinical Trial (SUNSHINE). Clinical Infectious Diseases 2020 71 p2581-2588

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**