

Date 10.10.19

Fidaxomicin (Dificlir®) for the Treatment of Clostridium Difficile Infection

The High Cost Drugs Subgroup discussed the above at its meeting on 28.09.19. The recommendation of this subgroup is as follows:

<p>Recommendation</p>	<p>Fidaxomicin (Dificlir®) may be considered as an option for use following a first or second relapse. i.e. as second or third line therapy. Fidaxomicin should be initiated by a microbiologist or under microbiologist recommendation.</p> <p>Fidaxomicin may also be considered for patients with severe CDI who are considered to be at high risk for recurrence as per the Public Health England Guidance. e.g. elderly patients with multiple comorbidities who are receiving concomitant antibiotics.</p> <p>Fidaxomicin is classed as GREEN+ drug on the GMMMG RAG list as suitable for prescribing by a GP on the advice of microbiologist.</p>
<p>Background</p>	<p>Fidaxomicin was approved in the EU in December 2011 for the treatment of C. difficile infections (CDI) also known as C. difficile associated diarrhoea. It is a novel antibiotic and is given orally at a dose of 200mg twice a day for 10 days for the treatment of Clostridium difficile (C. difficile) infection.</p> <p>Public Health England guidance for the management of Clostridium difficile infection was last updated in May 2013 and states that fidaxomicin should be considered for patients with severe CDI who are considered at high risk for recurrence; these include elderly patients with multiple comorbidities who are receiving concomitant antibiotics.</p> <p>In severe CDI cases not responding to oral vancomycin 125 mg qds, oral fidaxomicin 200 mg bd is an alternative; For recurrent CDI, oral fidaxomicin 200 mg bd is recommended; oral vancomycin 125 mg qds is an alternative</p> <p>A formal commissioning policy is required as fidaxomicin was added to the PBR Tariff Excluded Drugs List as a CCG commissioned drug from the 1st April 2019.</p>
<p>Efficacy and Safety</p>	<p>Fidaxomicin has been available as a licensed medicine in the UK since 2012 and the overall safety and tolerability are well described.</p>
<p>Cost Effectiveness/ Affordability</p>	<p>The NHS list price for the cost of treatment with fidaxomicin is £1350 for 200mg twice a day for 10 days compared to £91 for 500mg three times a day for 14 days of metronidazole and £131 vancomycin 125mg capsules four times a day for 14 days.</p> <p>Commissioning Arrangements: fidaxomicin is a high cost PbR excluded drug. CCGs are the responsible commissioner for fidaxomicin when used to treat</p>

	<p>Clostridium Difficile Infection.</p> <p>Anticipated numbers of patients for the above conditions is in the region of xx per year across Greater Manchester.</p>
Monitoring	<p>Monitoring and feedback will be from local antimicrobial stewardship groups. Because this drug requires antimicrobial consultant approval periodic clinical audit is required.</p>
Patient perspective	<p>Routine commissioning for this indication will mean that patients can quickly access an accepted treatment without any the need for an individual funding request to be processed.</p>

References

- Updated guidance on the management and treatment of Clostridium difficile infection. May 2013. Public Health England
https://assets.publishing.service.gov.uk/government/uploads/system/uploads/attachment_data/file/321891/Clostridium_difficile_management_and_treatment.pdf
- DIFICLIR 200 mg film-coated tablets. Summary of product characteristics. Date of revision of the text 17/05/2018. <https://www.medicines.org.uk/emc/product/4125>