Cx601 (Alofisel®) for complex perianal fistula in adults with non-active or mildly-active luminal Crohn's disease – second line

NIHR HSRIC

Record Status
This is a bibliographic record of a published health technology assessment. No evaluation of the quality of this assessment has been made for the HTA database.

Citation
NIHR HSRIC. Cx601 (Alofisel®) for complex perianal fistula in adults with non-active or mildly-active luminal Crohn's disease – second line. Birmingham: NIHR Horizon Scanning Research&Intelligence Centre. Horizon Scanning Review. 2015

Authors' objectives
Cx601 (Alofisel®) is intended to be used as a second line therapy for the treatment of complex perianal fistula in adult patients with non-active or mildly-active luminal Crohn's disease, where fistulas are refractory to conventional or biologic agents for Crohn's disease, or in patients intolerant to such treatments. If licensed, Cx601 will offer an additional novel, single administrative treatment option for such patients, a group that currently have few effective therapies available. Cx601 does not currently have Marketing Authorisation in the EU for any indication. The prevalence of Crohn's disease in the UK is approximately 50-100 per 100,000. There are currently at least 115,000 people in the UK with Crohn's disease, and the cumulative risk of perianal fistulas in patients 20 years after diagnosis is 26%. Among patients with Crohn's disease who develop perianal fistulas, one-third develop recurring anal fistulas, and two-thirds develop multiple fistulas. Crohn's disease is not curable, and the aim of therapy is to control manifestations of the disease, reduce symptoms, and to maintain or improve quality of life. Pharmaceutical options for the treatment of complex perianal fistula in patients with Crohn's disease include antibiotics accompanied by appropriate surgical drainage or in addition to immunosuppressant therapy. Biological agents are an option for second line treatment of fistulas. Surgical approaches such as advancement flap repair, fibrin glue, anal fistula plug, faecal diversion with fistula repair and various seton techniques are also options when treating complex fistula. Cx601 is currently in one clinical trial comparing its effect on fistula collections against treatment with placebo. The trial is expected to complete in April 2016.

Final publication URL

Indexing Status
Subject indexing assigned by CRD

MeSH
Humans; Adult; Crohn Disease; Rectal Fistula

Language Published
English

Country of organisation
England

English summary
An English language summary is available.

Address for correspondence
NIHR Horizon Scanning Research&Intelligence Centre, University of Birmingham, Institute of Applied Health
AccessionNumber
32016000345

Date abstract record published
03/03/2016