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MEDIA RELEASE

INFLAMMATORY BOWEL DISEASE: CHEAPER DRUGS PROVE SAFE AND CLINICALLY EFFECTIVE

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SWITCHING patients with inflammatory bowel disease (IBD) from originator to biosimilar infliximab is not only safe and effective, but could also result in significant savings to both patients and the Pharmaceutical Benefits Scheme, according to research published online today by the *Medical Journal of Australia*.

Infliximab and other agents are clinically effective for a range of chronic disease indications, including moderate to severe IBD, however they are expensive, accounting for as much as 64% of IBD-related health care costs, wrote the authors, led by Dr Craig Haifer, a gastroenterologist at St Vincent's Hospital Sydney and the University of Sydney.

"During 2015–16, expenditure for biologic medications in Australia was estimated to total at least $2.3 billion, and cost reduction strategies are needed to ensure the sustainability of biologic therapies for Australian patients," Haifer and colleagues wrote.

"One approach to reducing pharmaceutical expenditure is using less expensive biosimilar medicines."

The action of a biosimilar medication *in vitro* is very similar to that of the reference product, and there should be no clinically meaningful differences in potency, purity, or safety.

Haifer and colleagues conducted their research across seven Australian hospitals over 48 weeks, from May 2017 to October 2019. Participants were adults (18 years or older) with IBD receiving maintenance originator infliximab, who had been in steroid-free clinical remission for at least 12 weeks. The intervention group consisted of 204 patients in four hospitals who were switched from originator to biosimilar infliximab (CT-P13). The 141 participants in the other three hospitals continued to receive originator infliximab, and they were the control group.

"Ten in the control group (7%) and 16 patients switched to CT-P13 (8%) experienced clinical deterioration … [however] the adjusted risk difference [was] within our pre-specified non-inferiority margin of 15 percentage points," they reported.

"Serious adverse events leading to infliximab discontinuation were infrequent in both the switch (6, 3%) and control (6, 4%) groups."

The authors also found that their results had "significant health economic implications".

"At study commencement (May 2017), the PBS reimbursed $574.85 per 100 mg infliximab vial; at study conclusion (October 2019), the rate was $320.71 per vial," they wrote.

"On the basis of six PBS-funded 8-weekly infliximab infusions over 48 weeks per patient, the estimated annualised cost to the PBS for the entire study group (total of 1547 vials) in May 2017 was $5.34 million, and $2.98 million in October 2019.

"That is, the estimated annual cost to the PBS was $2.36 million lower in October 2019 (44%), or $6837 per patient-year of infliximab therapy.

“This cost saving, independent of whether originator or biosimilar infliximab or CT-P13 is used for therapy, was the result of increased market competition following the introduction of biosimilar infliximab in Australia for the treatment of IBD.”

Haifer and colleagues wrote that their research would be reassuring for clinicians and patients.

“The results indicate that it is safe to switch clinically stable patients with moderate to severe IBD from originator to biosimilar infliximab.

“The introduction of the infliximab biosimilar CT-P13 has also led to a considerable reduction in the PBS-listed price for infliximab, resulting in millions of dollars in estimated cost savings for the PBS. It is therefore anticipated [these results] will reassure both health professionals and patients that biosimilar infliximab is safe, clinically effective, and economical,” they concluded.

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