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OPINION PIECE

IBD patients access to effective therapy in South Africa - are we regressing back to the past?

Globally, autoimmune diseases are increasing, and a recent population-based study indicates that as many as 1 in 10 people in the UK live with an autoimmune disease.[1] If extrapolated to South Africa (SA), these data equate to 6 million South Africans, a number not far behind estimates for HIV infection.

Consistent with this, data from the IBD Africa Registry shows the incidence of IBD has increased exponentially over the past 50 years.

Biological therapy for the treatment of inflammatory bowel disease (IBD) became available in South Africa in 2000 and has markedly revolutionised therapy, making remission targets such as complete resolution of symptoms, normalisation of disease biomarkers and mucosal healing achievable. As a result, permanent gut damage, resulting in disability, can be avoided and now, people living with IBD, can enjoy a normal quality of life.

South Africa is fortunate to have most of the advanced IBD therapies (biologics and small molecules) registered by SAHPRA. Importantly, biosimilars are now available, that have reduced drug prices down by as much as 60%.

The convergence of increasing patient numbers, effective therapies and declining drug prices offers some hope to the thousands of people living with IBD in SA. Regrettably, the reality is that most patients in SA will never receive these drugs despite a legal framework that allows for access to advanced IBD therapies in the private sector and the approval of anti-TNF drugs on the National Essential Medicines List for tertiary and quaternary level care.

Michael is 32-year-old doctor working in an ER at a public hospital. He was diagnosed with ulcerative colitis (UC) at the age of 18. His treatment was according to standard treatment algorithms - first 5-ASA medication, then an immunomodulator and progressing to an anti-TNF drug. He developed disseminated TB on his anti-TNF and required a prolonged hospital admission. He was unable to work for several weeks. In this scenario vedolizumab, a gut specific biologic, was the ideal choice of treatment for his UC and he received this medication through an early access pre-registration programme. He remained in excellent remission on vedolizumab and when the drug was registered in SA his medical aid, a profession specific medical fund, was approached to continue his treatment. This was declined unless he upgraded his plan – at a cost of R12 000 a month. This was well beyond the means of a junior public service doctor. He challenged this decision through the Council of Medical Schemes (CMS). The fund did everything within its power to draw out the CMS process with delays and last-minute appeals. Nevertheless, Michael persevered and won the right to receive funding for his treatment. It became abundantly clear that the Fund would not accept the CMS rulings and further legal challenges were planned. At this point Michael abandoned his fund and changed to Discovery Health. He was later approved for fully funded treatment. The very next day another similar case against Michael's previous fund was started through the CMS for access to biologic therapy. Because these rulings are not precedent setting, each and every case needs to be adjudicated individually. The CMS process is heavily stacked against the patient. For most patients struggling with a chronic condition the process is very onerous and daunting. Processes tend to be drawn out over years. This puts the individual patient at a significant disadvantage and very few have the stamina or emotional resilience to go the distance.

Switching to a scheme that funds biologics is the path of least resistance. This allows well recalcitrant schemes to collect contributions from members over many years but de facto palm them off on other schemes when funding for autoimmune diseases is required. This is untenable and morally wrong.

Ultimately, schemes' refusal to fund non formulary treatment for patients whose clinical circumstances trigger these regulations comes down to a difference in interpretation. The regulations in question unequivocally state that exceptions to cost-containing measures must be funded where other available treatments either fail or harm the member. In response to CMS complaints, schemes routinely put forward a variety of reasons why this clearly stated obligation excludes treatments like biologics. The Regulator in turn dismisses these reasons and rules in favour of the member. Hearing each case individually instead of taking a stand on wide-spread abuse by a scheme is justified by the Regulator on the grounds that cases are based on medical merits. But schemes do not question the clinical appropriateness of these treatments, just their obligation to fund. Fedhealth recently went so far as to confirm in writing its intention to appeal all future CMS Regulation 15I(c) and 15H(c) rulings as a matter of course, despite clinical appropriateness, effectively rendering the Regulator's prescribed remedy a nonstarter for members denied their rights.

It was largely in response to this abuse by medical schemes that the Autoimmune Alliance was formed. Both Arthritis Kids SA and IDB Africa have long histories of treatment advocacy and through the Alliance, continue to apply pressure on the Regulator to take

an official stand on escalating refusals to fund despite a statutory obligation.

The January 2024 decision by a large funder was very concerning if not devastating for IBD care. A range of changes curtailing access to patients in sustained remission on biologic therapy and potentially denying biologics to newly diagnosed patients, was instituted. The Council for Medical Schemes approved the scheme changes at face value, but it is unlikely the potential impact of members losing access to essential treatment, for which they had already qualified, was apparent.

There have been assurances, but the reality has been somewhat different. Patients are now needing to contribute significant co-payments for ongoing therapy or fund their treatment in full. The net effect is that gastroenterologists are observing more frequent admissions for IBD, reliance on steroids to treat patients and discussions regarding surgery are again surfacing with gastroenterology practices trying to deal with the results. IBD Africa and the Autoimmune Alliance have provided compromises and temporary solutions but unfortunately have not been met with any positive responses or meaningful engagement.

There is a seeming lack of recognition that autoimmune diseases are increasing, and due to compounding prevalence, more and more patients will require care in the future. Organisations such as the Autoimmune Alliance of SA, IBD Africa and Arthritis Kids South Africa are very willing to partner in finding solutions. What we have currently is a retrogressive step back into the past for care. While cost containment is the short-term objective, the long-term effect is potentially greater spend on those with IBD and other autoimmune diseases. Given steroid-related complications and disability associated with IBD surgery. Our major concern of the policy move is a paradoxical increase in healthcare costs in the future given the silo financial functioning by funders. More especially are our patients who are now unable to access effective, evidenced based, dramatic life quality improving treatment.

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Reference

1. Da-Peng Li, Han YX, He YS, et al. A global assessment of incidence trends of autoimmune diseases from 1990 to 2019 and predicted changes to 2040. Autoimmunity Reviews. 2023;10-01.