MAY 2026

RULINGS ISSUED BY THE OFFICE OF THE REGISTRAR

The CMS hereby publishes summaries of rulings recently issued by the Complaints Adjudication Unit in respect of complaints lodged against regulated entities, in terms of Section 47 of the Medical Schemes Act.

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M obo L v DISCOVERY HEALTH MEDICAL SCHEME

Declined funding

The complaint concerns the Scheme's decision to decline funding for Pembrolizumab (Keytruda®) for the treatment of the Member's diagnosis of advanced pancreatic adenocarcinoma. According to the Complainant, the Member was diagnosed with advanced pancreatic adenocarcinoma and has failed both first and second-line treatments, however, the Scheme refuses to fund Pembrolizumab® to manage her condition. Therefore, the Complainant requested the Registrar to adjudicate this matter on urgent basis and compel the Scheme to fund the Member's next line of treatment without any penalty.

In response, the Scheme submitted that the Member is on the Classic Priority option, which provides oncology cover in 2025 in line with SAOC and ICON treatment guidelines. These guidelines include

different levels of care, with full cover for essential/PMB-level treatments and additional treatments subject to motivation. The Scheme indicated that the Members must obtain chemotherapy and supportive medication through the Oncology pharmacy designated service provider (DSP). The plan also offers an Oncology Innovation Benefit, which covers selected treatments subject to clinical criteria, with funding limited to 50% of costs up to specified thresholds (R375,000 or R250,000 depending on the plan). The Scheme explained that the Member has been registered for oncology benefits since 2023 for pancreatic cancer (a PMB condition) and has a history of breast cancer. A request was submitted for funding Pembrolizumab® for advanced pancreatic cancer which was declined on the basis that Pembrolizumab is not covered for this condition under the Scheme's oncology benefit, is considered off-label, is not supported by ICON guidelines, and is not a PMB level of care. It stated that alternative treatments are available. The decision to decline funding was therefore upheld.

The issue for determination was whether the Scheme acted correctly in declining funding of Pembrolizumab® for the Member's condition.

The matter was reviewed alongside the submissions from both parties and referred to the CMS Clinical Review Committee (CRC). The CRC confirmed that pancreatic cancer falls under PMB provisions only where there is a five- year survival rate exceeding 10% for the relevant therapy, which was not the case for Pembrolizumab®. Furthermore, the treatment is not SAHPRA-registered for pancreatic cancer, is considered off-label, and is not supported by ICON protocols. Regulation 15H(c), which allows exceptions when standard treatments fail or cause harm, does not apply because Pembrolizumab® is not an approved or evidence-based treatment for this condition. Therefore, the Scheme could not be compelled to fund it. The Schemes' decision aligned with Regulation 8(4), allowing the use of treatment protocols and pre-authorisation to ensure cost-effective care. While the treating provider's recommendation is acknowledged. Accordingly, the refusal to fund Pembrolizumab® was justified based on clinical evidence, CRC advice, and applicable legislation.

A ruling was therefore issued confirming that the Scheme had no legal obligation to fund Pembrolizumab® for the Member's condition, as this treatment is not PMB level of care for and is not applicable in terms of Regulation 15H(c) for her condition. The complaint was hereby dismissed.