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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Z v DISCOVERY HEALTH MEDICAL SCHEME

Protocol

The complaint concerned the decision of the Scheme in declining funding Cotellic for the management of the Member's condition, *Multifocal and unisystemic Langerhans-cell histiocytosis*; ICD-10 Code C96.5 and the Scheme's alleged poor service regarding delays in approving the funding requests.

In responding to the complaint, the Scheme indicated that due to the complex nature of the matter, clinical information was sent to an independent external panelist for review. The Scheme further advised that where there is a delay in receiving feedback from an external panelist, there will be a subsequent delay in its final funding decision. The Scheme stated further that it maintained its decision to decline funding because there is insufficient clinical evidence available to support the use of Cotellic for the Member's condition. According to the Scheme, its decision to decline funding is supported by its scheme rules which state the following:

> *With due regard to the Prescribed Minimum Benefits as set out in Regulation 8 and these Rules and unless otherwise provided in a defined benefit and in accordance with the Scheme's treatment guidelines and managed care criteria, expenses incurred in connection with Rule 15.12 of the Main Body as well as any of the following, will not be paid by the Scheme:*
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> > *1.22 healthcare services that do not meet the Scheme's clinical protocols, provided that such protocols are in accordance with evidence-based medicine, taking into account considerations of cost-effectiveness and affordability and international and/or industry best practice".*

The issue which fell for determination was whether the Scheme was correct in declining to fund Cotellic for the management of the Member's condition.

Upon investigation, the complaint was referred to our Clinical Review Committee ("CRC") to confirm whether the requested Cotellic is PMB level of care for the Member's condition. CRC advised that the Member's condition is PMB however, according to Roche, which is the manufacturer, Cotellic® (cobimetinib) is a kinase inhibitor indicated for the treatment of patients with BRAF V600E or BRAF V600K mutation-positive advanced melanoma, in combination with vemurafenib.

Considering the manufacturer's indications, Cotellic® (cobimetinib) is not indicated for "Multifocal and unisystemic Langerhans-cell histiocytosis. CRC advised that the treatment component specified for DTP code 196S does not include chemotherapy or immunotherapy. According to point 2 (i) of the explanatory notes and definitions to Annexure A of the PMB Regulations, "tumour chemotherapy" is excluded from the generic medical/surgical management categories unless otherwise specified.

It was to this end that a ruling was issued confirming that the Scheme is correct in declining funding for Cotellic. The complaint was dismissed.