8 December 2021

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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N v GOVERNMENT EMPLOYEES MEDICAL SCHEME

Non-formulary drug

The Complainant submitted a complaint to the Office of the Registrar against the Scheme for rejecting to approve full funding of Xultophy®, a drug prescribed by her treating provider.

The Complainant, a known Type 2 Diabetic, indicated that prior to the provider prescribing the drug, her sugar levels were unstable. The provider reportedly prescribed the drug as an alternative insulin to test whether her sugar levels will normalise. The Complainant proceeded to purchase the drug out of pocket and used it for two weeks, where after she was assessed by her treating provider. She stated that her sugar levels had improved and her treating provider recommended that she continue with the drug, however despite being made aware of this, the Scheme maintained its decision to decline funding for Xultophy®.

The matter was referred to the Scheme for a formal response in terms of section 47(1) of the Medical Schemes Act, in its response, the Scheme confirms that it declined the request as the drug is not covered on the chronic medicine benefit. According to its scheme rules, this medicine management is classified as an exclusion, and therefore not covered by the chronic medicine benefit.

The Scheme confirmed further that the Complainant would meet the criteria for funding, however only if less costly alternatives were considered, namely Tresiba® and Byetta®.

The matter was subsequently referred to the CMS Clinical Review Committee ("CRC"), who confirmed that the Complainant's condition is classified as PMB, however the treatment (Xultophy®) is not regarded as PMB level of care.

PMB treatment for the condition, non-insulin-dependent diabetes mellitus without complications, is specified by the therapeutic algorithm in Annexure A to the Regulations. The algorithm explains that if a patient is not adequately controlled on Metformin® (Glucophage), Sulphonylurea can be added to treatment to optimise therapy. However, if the blood glucose remains uncontrolled despite the

dual therapy; insulin therapy may be considered. The algorithm does not specify the use of Xultophy® therefore rendering it non-PMB level of care.

There was also no suggestion or clinical evidence provided to suggest that the Scheme's available formulary drugs, were ineffective, caused harm or could cause harm. Short of proof of such confirmation, the Scheme could not be compelled to fund Xultophy® in full as the provisions of Regulation 15I (c) are not met. It was on this basis that the matter was dismissed.