BEFORE THE APPEAL COMMITTEE OF THE COUNCIL FOR MEDICAL SCHEMES HELD VIA THE MICROSOFT TEAMS VIDEO AND AUDIO CONFERENCE TECHNOLOGY INSTITUTED IN TERMS OF MEDICAL SCHEMES ACT NO 131 OF (1998) - CASE NUMBER (CMS 83705)

In the matter between:

MEDIHELP MEDICAL SCHEME	**APPELLANT**
AND	
REGISTRAR	**1ST RESPONDENT**
MR T	**2AND RESPONDENT**
DATE OF HEARING:	**10 JULY 2024**
DATE OF RULING:	**27 JULY 2024**

RULING AND REASONS

THE PARTIES.

1. The Appellant is Medihelp Medical Scheme, the medical scheme registered in terms of section 24 of the Medical Schemes Act 1 of 199. Ms. A appeared on behalf of the scheme as its Legal Advisor.

2. The first Respondent is the Registrar of the Council for Medical Schemes ("CMS"). The Council for Medical Schemes is an autonomous body established in terms of the Medical Schemes Act 1 of 1998.

3. The second respondent is Mr T, who is the member in good standing with Medihelp Medical Scheme.

4. The Council for Medical Schemes (CMS) sole purpose, is to regulate the Medical Schemes industry with its principal place of business located at the Eco- Park Estate, Centurion.

APPLICATION TYPE AND RELIEF SOUGHT

5. The appellant makes this application in terms of section 48(1) of the Act. This section provides –

> *"(1) Any person who is aggrieved by any decision relating to the settlement of a complaint or dispute may appeal against such decision to Council."*

6. The Appeals Committee heard the Appeal on 10 July 2024 *via* audio and video conferencing link.

7. The hearing concerns the merits of the appeal filed by the scheme Legal advisor Ms A.

8. The appellant seeks relief on the following:

8.1 That the Appeals Committee, to set aside the decision of the registrar on grounds that, Lemtrada does not constitute PMB level of care in terms of Department of Health Guidelines of 2013.

8.2. That the appeals committee, to rule that, the registrar cannot compel the scheme to fund expenses incurred outside the scheme, benefit obligation in respect of its rules of section 32 of the Medical Schemes Act 1 of 1998.

8.3. That the appeals committee, to rule that the scheme correctly imposed co-payment for the funding of Lemtrada as treatment option for the members condition due to it not being PMB level of care and members benefit option.

RELEVANT STATUTORY AND REGULATORY PROVISIONS.

9. The relationship between the member and the scheme is governed by the terms of the contract ('*the scheme rules"*) that the member concluded with Medihelp.

10. The Contract between the member and the Scheme is governed in terms of section 32 of the Medical Schemes Act 1 of 1998.

WIDE APPEAL

This is the wide appeal. The Appeals Committee may consider the matter afresh and is not restricted to the record of the proceedings that were before the registrar.

THE ISSUE IN DISPUTE

11. The issue to be decided by the appeals committee, is whether the registrar in his ruling, was correct in instructing the scheme to fund lemtrada in full without co-payment.

REGISTRARS RULING

12. In the ruling, the Registrar stated that, Medihelp has to fund Lemtrada in full without co-payment. Furthermore, this was after the complainant asked the registrar to intervene and direct the scheme to fund either Lemtrada or Bonspri in full without co-payment as the Prescibed Minimum Benefit (PMB).

13. Moreover, in the ruling, the Registrar ordered that Lemtrada constitute PMB level of care and concurred with the findings of the Clinical Review Committee that Regulation 15I(c) applies in the case of Mr T, that the scheme must fund Lemtrada as PMB level of care for the member's condition.

14. In addition, in endorsing the findings of the CRC, the registrar stated that:

"Based on the 2013 South African guideline on Multiple Sclerosis, IFN-beta-1b (Betaferon) and glatiramer acetate (GA) (Copaxone) are indicated as first-tier treatments. If relapses continue, therapy escalation with either Fingolimod or Natalizumab can be considered. Mitoxantrone should be reserved as a third-tier

therapy. "Considering the above guidelines, Mitoxantrone should be considered as third-tier therapy. However, due to the cardiotoxic risk of Mitoxantrone, Lemtrada (alemtuzumab) is PMB level of care for the member's condition.

15. The registrar further stated in the ruling, that, in terms of the provisions of Regulation 8(1) of the Act, the diagnosis, treatment and care of a PMB condition must be paid in full by a medical Scheme and it read as follows:

"8. Prescribed Minimum Benefits. — (1) Subject to the provisions of this regulation, any benefit option that is offered by a medical scheme must pay in full, without co-payment or the use of deductibles, the diagnosis, treatment and care costs of the prescribed minimum benefit conditions."

SUBMISSION BY APPELLANTS.

16. The appellants submitted during the hearing that, Medihelp declined the funding of Lemtrada as this treatment is excluded in the scheme's funding protocols for all of its plans.

17. The scheme in its appeal papers, stated that, lemtrada is not PMB level of care and not funded on any option. The scheme advised that Bonspri was approved up to December 2023 and it will be funded with a co-payment in 2024, a decision vehemently opposed by the member.

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[1] Regulation 15I (c) and Regulation 8 (1) of the Medical Schemes Act 1 of 1998.

18. The Scheme stated that, Lemtrada was declined as it is not included in the treatment algorithm of multi sclerosis in the Regulations. Furthermore, it is not in the EML or the Scheme's treatment protocol.

19. Furthermore, Lemtrada is not included in the Chronic Disease List (CDL) therapeutic algorithm for multiple sclerosis published in the Regulations under the Medical Schemes Act 131 of 1998, and therefore does not qualify for Prescribed Minimum Benefits (PMBs).

20. The scheme submitted that, Lemtrada is also not included in the National Department of Health's Tertiary and Quaternary Essential Medicines List (EML) of March 2023 or the NAPPI Coded Essential Medicines List (EML) published by MediKredit in June 2023.

21. According to the scheme's version, Mr T was informed that Bonspri had been approved on his current plan, MedPrime, as an out-of-protocol exception until 31 December 2023.

22. The scheme also mentioned in the communication to Mr T that, further funding would be considered after 31 December 2023 if he were to upgrade to a plan that provides funding for biological medicines.

23. Furthermore, the scheme stated that, If Mr T remains on the MedPrime plan, which does not offer funding for biological treatment, Medihelp will fund the amount which

will be in line with current PMB level of care available in the public sector and this translates to a 25% co-payment.

24. The scheme submitted that, it approved funding of Bonspri without a co-payment for Mr T on his current plan, MedPrime, as an out-of-protocol exception for the period 21 September to 31 December 2023, but, thereafter, 25% co-payment will be imposed.

SUBMISSIONS BY RESPONDENTS.

25. The member, Mr T is vehemently opposed to the scheme decision to impose a 25% co-payment as he believes that, he is not obligated to a further payment since his condition constitute the PMB level of care.

26. The member further submitted that, treatment bonspri was not effective in treating his condition, hence his request to continue using the Lemtrada drug.

27. The member submitted that, the scheme decision that he has to upgrade his plan in order to be entitled for the benefit option without a further 25 % co-payment is unreasonable and unjustifiable.

28. The member believes that he is not obligated for any payment and the scheme has to fund Lemtrada or bonspri in full as the PMB level of Care without imposing any co-payment.

LEGAL FRAMEWORK AND EVALUATION.

29. In terms of regulation 15I (c) of the Medical Schemes Act 1 of 1998, it state that, provision must be made for appropriate substitution of drugs where a formulary drug has been ineffective or causes or would cause adverse reaction in a beneficiary, without penalty to that beneficiary.

30. Furthermore, regulation 8 (1) state that, subject to the provision of this regulation, any benefit option that is offerred by a medical scheme must pay in full, without co-payment or the use of deductibles, the diagnosis, treatment and care costs of the prescribed minimum benefit conditions.

ANALYSIS.

31. The issue that falls for determination by the appeals committee, is whether regulation 15I (c) is applicable in the present case and on whether the scheme is justified in its decision not fund Lemtrada drug in full.

32. The scheme was asked to provide an alternative on ground that the member indicated that, the bonspri was not effective hence his request to continue using Lemtrada drug.

33. During the hearing, the scheme was asked to provide the reasons or the basis for its decision not to fund Lemtrada in full and on why regulation 15I (c) is then not applicable to the member, and what were the grounds for imposing co-payment.

34. The scheme indicated that, Lemtrada did not constitute a PMB level of care and in turn, the Registrars ruling indicated that Lemtrada is the PMB level of Care.

35. The scheme submitted that, it approved funding of Bonspri without a co-payment for Mr T on his current plan, MedPrime, as an out-of-protocol exception for the period 21 September to 31 December 2023, but, thereafter, 25% co-payment will be imposed.

36. In the ruling, the order state regulation 15I (c), which indicate that, the provision must be made for appropriate substitution of drugs where a formulary drug has been ineffective or causes or would cause adverse reaction in a beneficiary without penalty to that beneficiary.

37. In its appeal papers and submissions before the appeals committee, the scheme submitted that, it did not impose co-payment on bonspri and thereafter, the co-payment will be imposed to the member.

38. During the hearing, it was put to the scheme that, in terms of regulation 15I (c) where the substitution or alternative has been ineffective or would cause adverse reaction to the beneficiary, such substitution must be done without penalty to that benefficiary. The scheme was unable to provide the answer on the above question posed by the appeals panel.

39. Furthermore, the registrar in his ruling stated the following:

"Based on the 2013 South African guideline on Multiple Sclerosis, IFN-beta-1b (Betaferon) and glatiramer acetate (GA) (Copaxone) are indicated as first-tier treatments. If relapses continue, therapy escalation with either Fingolimod or Natalizumab can be considered. Mitoxantrone should be reserved as a third-tier therapy. "Considering the above guidelines, Mitoxantrone should be considered as third-tier therapy. However, due to the cardiotoxic risk of Mitoxantrone, Lemtrada (alemtuzumab) is PMB level of care for the member's condition.

40. The above analysis provided by the Clinical Review Committee reading in line with regulation 15I (c) and regulation 8 (1) of the Medical Schemes Act 1 of 1998, the reasons and the basis for the funding of Lemtrada drug in full is justifiable.

FINDINGS.

During the hearing, the appeals committee panel considered all the facts, Registrars ruling, Clinical Review Committee opinion, submissions of both the appellants and respondents, provisions of the Act, its Regulations and the registered Scheme rules of Medihelp and therefore, present the following findings:

41. The appeals committee finds that, the scheme cannot impose co-payment on Lemtrada in line with regulation 15I (c) of the Medical Schemes Act of 1998.

42. The appeals committee is satisfied, and finds that, the scheme was incorrect in its submission when it decided to impose co-payment on Bronspri and Lemtrada drug in terms of regulation 15I (c) of the Act.

43. The appeals committee is satisfied and finds that, in terms of regulation 15I (c) of the Medical Schemes Act 1 of 1998, it state that, provision must be made for appropriate substitution of drugs where a formulary drug has been ineffective or causes or would cause adverse reaction in a beneficiary, without penalty to that beneficiary.

44. The appeals committee finds that, in the case of the beneficiary, Mr T, bonspri was not effective hence his request to use Lemtrada drug, it is also found that, Lamtrada drug, due to the cardiotoxic risk of Mitoxantrone, Lemtrada (alemtuzumab) is PMB level of care for the member's condition.

45. The scheme is ordered to refund the member where co-payment was imposed in both the bonspri and Lemtrada drug.

ORDER

46. Accordingly, the appeals committee makes the following order:
    46.1 The decision of the registrar is upheld.
    46.2. The appeal is dismissed
    46.3. There is no order as to costs.

DATED AT CENTURION ON THIS 27TH JULY 2024.

XK Ngobese

Dr. Xolani Ngobese (on behalf of the appeals committee). **CONCURRING** – Dr T Mabeba, Miss M Ramagaga, Dr S Naidoo, Miss P Beck and Dr K Chetty.