IN THE APPEAL BEFORE THE APPEALS COMMITTEE OF THE COUNCIL FOR MEDICAL SCHEMES

HELD VIA THE MICROSOFT TEAMS VIDEO AND AUDIO CONFERENCING TECHNOLOGY

(Instituted in terms of the Medical Schemes Act No.131 of 1998)

Case number: **CMS/80308**

In the matter between:

K	**APPELLANT**
And	
SOUTH AFRICAN POLICE MEDICAL SCHEME (POLMED)	**1ST RESPONDENT**
REGISTRAR OF MEDICAL SCHEMES	**2ND RESPONDENT**

ORDER AND REASONS

THE PARTIES

1. The Appellant is K, ("the Appellant or the member") an adult male, resident in Parys in the Free State. The Appellant was represented by Mrs C, the daughter of the Appellant, duly authorised to represent the Appellant.

2. The Appellant is a member of the scheme in terms of the definition accorded to a "member'" under the Medical Schemes Act 131 of 1998 ("the Act.")[1]

[1] '"member" means a person who has been enrolled or admitted as a member of a medical scheme, or who, in terms of the Rules of a medical scheme, is a member of such medical scheme.

3. The 1st Respondent is The South African Police Medical Scheme, ("the Scheme or Polmed") with its principal place of business at Roodepoort, Gauteng. Polmed is a Medical Scheme duly registered and regulated under the Medical Schemes Act Act 131 of 1998 ("the Act.")

4. The 1st Respondent was represented at the hearing by Ms D, the legal representative of the scheme, duly authorised.

5. The 2nd Respondent is the Registrar of the Council for Medical Schemes ("the Registrar") with its principal place of business at Eco Park, Centurion.

6. The 2nd Respondent did not appear at the hearing and agreed to abide by the decision of the Appeals Committee.

INTRODUCTION

7. This is an appeal in terms of section 48(1) of the Council for Medical Schemes Act 31 of 1998 ("the Act") against a decision of the Registrar dated 17 November 2022.[2]

8. This section provides that:
"(1) Any person who is aggrieved by any decision relating to the settlement of a complaint or dispute may appeal against such decision to the Council."

9. The Appeal arises out of the Registrar's ruling that the scheme's decision to decline funding of the Edwards Intuity Elite Valve System ("EIEVS") as recommended by the member's Cardiothoracic surgeon is justified.

10. The Appeal Committee heard the Appeal on 3 June 2024 via an audio and video conferencing link.

11. The Appellant seeks an order for the following relief:

[2] Page 194 of the Bundle

11.1 That *the "First Respondent be instructed to fund, in full the EIEVS procedure in view and consideration of Regulations 8(1), 15(h)(c) and 15(l)(c)" of the Act*.[3]

FACTUAL BACKGROUND

12. The Appellant is a 73 year old male diagnosed with Aortic Valve Stenosis, a heart condition, listed in the Regulations to the Act as a Prescribed Minimum Benefit condition ("PMB.")

13. On 21 May 2022, the scheme received an authorisation request for the Appellant's admission on 26 May 2021, to the Flora Clinic, for an aortic valve replacement procedure. The scheme approved the procedure; and the incidental prosthesis used in an open-heart procedure. The authorisation letter addressed to the Appellant, by the scheme, included a caveat that there are no benefits available for a Percival Suture-less Aortic Valve.

14. On 27 May 2021, the scheme received a request to change the admission date of the Appellant to 30 May 2021, together with a quotation for a Vasoview Hemporo 2 Valve, in the amount of R20 987.62, which request was accordingly approved by the scheme.

15. On 2 June 2021, the scheme received another request from the Appellant, together with a motivation from Dr B, the Appellant's Cardiothoracic Surgeon, for the approval of the Edwards Intuity Elite Valve System ("EIEVS") at a cost of R103 500.00.

16. The scheme informed the Appellant in a letter dated 21 May 2021, that it declined to fund the EIEVS based on its funding guidelines/rules, its protocol based on aortic valve replacements; and because the funding of the EIEVS is not a PMB level of care.

17. The Appellant proceeded with the EIEVS procedure at the Flora Medi Clinic. A claim of R 405 612. 77 was submitted by the Appellant to the scheme. The scheme paid the amount of R302 112.77 for the procedure, leaving a shortfall of R97 928.00.

[3] Page 14 paragraph 58 of the Appellant's Heads of argument.

RELEVANT STATUTORY AND REGULATORY PROVISIONS

18. The relationship between the member and the scheme is governed by the terms of the contract ("the schemes rules") that the member concluded with the scheme. The contract in turn is governed by the Act and the regulations (as amended) made in terms of the Act.

19. The question that the Appeals Committee must consider is whether the scheme acted lawfully. In doing so we will assess whether the conduct of the scheme meets the requirements of the Act, read with the Regulations promulgated in terms of the Act specifically the following:

20. Section 32 of the Act which stipulates as follows- *"Binding force of rules.—The rules of a medical scheme and any amendment thereof shall be binding on the medical scheme concerned, its members, officers and on any person who claims any benefit under the rules or whose claim is derived from a person so claiming."*

21. The definition of "*managed health care*" as defined in the Regulations of the Act-
"managed health care" means clinical and financial risk assessment and management of health care, with a view to facilitating appropriateness and cost-effectiveness of relevant health services within the constraints of what is affordable, through the use of rules-based and clinical management-based programmes."

22. Section 29 of the Act which stipulates as follows-
"Matters for which rules shall provide -
The Registrar shall not register a medical scheme under section 24, and no medical scheme shall carry on any business, unless provision is made in its rules for the following matters 29(1)(o) the scope and level of minimum benefits that are to be available to beneficiaries as maybe prescribed."

23. *Regulation 7 of the MSA which defines a PMB as- ''benefits contemplated in Section 29 (1) (0) of the Act and consist of the provision of diagnosis, treatment and care costs of – a. The diagnosis and treatment pairs listed in Annexure A, subject to any limitations specified in Annexure A; and b. any emergency medical condition.''*

24. *Regulation 8(1) of the Act stipulates that: 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 condition."

25. Regulation 15 of the Act which defines "*evidence-based medicine"* as the-
"*conscientious explicit and judicious use of current best evidence in making decisions about the care of beneficiaries whereby individual clinical experience is integrated with the best available external clinical evidence from systematic research*."

26. Regulation 15 (H)(c) of the Act that relates to protocols and stipulates that -
"Protocols- if managed health care entails the use of a protocol-
(c) provision must be made for appropriate exceptions where a protocol has been ineffective or causes or would cause harm to a beneficiary, without penalty to that beneficiary."

27. Regulation 15I(c) of the Act which *stipulates 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."

WIDE APPEAL

28. This is a wide appeal. The Appeal Committee may therefore consider the matter afresh and is not restricted to the record of proceedings that were before the Registrar.

29. The burden of proof rests on the Appellant who must prove on a balance of probabilities that the appeal should succeed.

THE ISSUE IN DISPUTE

30. The issue in dispute is whether the Registrar was justified in upholding the schemes decision to decline funding EIEVS on the basis that EIEVS is not PMB level of care; and because funding thereof is neither provided for in the scheme rules or in the Regulations.

31. It is therefore to be determined whether the scheme acted in contravention of the Act read with both the Regulations and the scheme rules by not funding EIEVS, in full, as a PMB level of care.

THE APPELLANT

32. The Appellant submitted that in 2021, he was diagnosed with severe aortic valve stenosis and ischemic heart disease.

33. Dr B, the Appellant's Cardiothoracic surgeon, in his letter of motivation to the scheme dated 2 June 2021, recommended that the Appellant undergo the EIEVS procedure for his coronary artery bypass surgery citing that the member suffered from hypertension and chronic venous insufficiency. Two other procedures were submitted to the scheme for approval prior to the EIEVS procedure recommendation, both of which were authorised by the scheme.

34. Payment for the EIEVS procedure was however declined by the scheme based on the scheme rules; the Act; and because EIEVS is not a PMB level of care.

35. In terms of section 47 of the Act, the member filed a complaint with the Registrar of the Council for Medical Schemes. The Registrar consulted the CMS Clinical Review Committee ("CRC") who expressed the view that, that the member must be screened into the TAVI programme by a multidisciplinary team; and the member must be found to have severe aortic stenosis with a risk benefit diagnosis favouring TAVI, over open-heart surgery.

36. The Registrar dismissed the complaint despite the member's co-morbidities and heart condition, ruling that the PMB level of care for the member's condition was aortic valve replacement and not EIEVS.

37. The Appellant placed on record that it is undisputed that aortic valve replacement is a PMB condition.

38. The Appellant submitted that Regulation 8 of the Act stipulates that payment for a PMB condition must be paid "*in full*." To this end, regulations 15A to 15K has application for managed care and for the use of a designated service provider to manage the costs associated with payment "*in full*" as stipulated in regulation 8.

39. In terms of section 29(1)(o), the Appellant argues that no medical scheme shall carry on business unless it provides for the scope and level of minimum benefits that are prescribed by the Act and the regulations; and thus it is contrary to the Act read with the Regulations for the scheme to decline the funding of EIEVS with due regard also to the member's medical condition and co-morbidities.

40. The Appellant in support of the appeal, referred the Appeals Committee to the case of The Council for Medical Schemes v Genesis Medical Scheme[4] wherein the court ruled that-

"40.1 schemes are not governed solely by that scheme's rules but also by the obligations imposed by statute upon medical schemes; and

40.2. the court found that these latter obligations cannot be evaded by a medical scheme purporting to contract with its members by prescribing rules having a contrary effect."

41. The Appellant argued that although the Act states that a scheme is bound by its rules, if one or more of those rules are contrary to law, the law must take precedence.

42. In further support of its submission the Appellant referred to Regulation 15 of the Act and to the definition of "*evidence based*" medicine; and to Regulation 15H(c) of the Act that stipulates that: "*provision must be made for appropriate exceptions where a protocol has been ineffective, or causes or would cause harm to a beneficiary, without penalty to that beneficiary."* Regulation 15I(c) of the Act also provides for instances where it would be justified to deviate from the list of medications on a Scheme's formulary if such formulary medicines are, inter alia, ineffective, or would cause harm to the member.

43. The Appellant referred to numerous studies that demonstrate the efficacy of EIEVS. According to the Appellant, the requirement of "*evidence-based medicine*" therefore cannot be overridden by an explanatory note to the regulations, nor can it be used to short-circuit the very clear legislative imperatives found in, amongst others, regulation 15H. A scheme therefore cannot invoke a co-payment to a member when applying Regulation 15(H)(c) and 15(I)(c.

[4] 2016 (1) SA 429 (SCA). The Council for Medical Schemes v Genesis Medical Scheme (20518/2014) [2015] ZASCA 161; 2016 (1) SA 429 (SCA); [2016] 1 All SA 15 (SCA) (16 November 2015)- See Appeals Bundle at p 54-62.

44. The scheme per the Appellant, failed to take into account that Regulation 15(H)(c) and 15(I)(c) makes clear provision that where a treatment plan would fail and is not appropriate, as in the Appellant's case, open-heart surgery, the Appellant must be allowed to follow the appropriate treatment plan without being penalized.

45. The Appellant submits that EIEVS is a PMB level of care if regard is had to the co-morbidities of the member and based on the recommendation of the members Cardiothoracic surgeon, Dr B.

46. The Appellant further referred the Appeal Committee to the ruling in the Matter of Medshield and MSO v the CMS[5] where the Appeal Board confirmed the need for evidence-based medicine and exemptions where necessary.

47. In the matter K v Bonitas Medical Fund CMS 74095[6] the Fund declined the TAVI procedure funding and approved an open-heart surgery procedure, also known as Surgical Aortic Valve Replacement ("SAVR"), on the basis that TAVI is not a standard procedure prevailing in the state hospitals, thus not a PMB level of care. This decision was overturned on appeal where it was held that TAVI should be considered as one of the standards of care for a PMB condition.

48. Accordingly, based on the aforementioned CMS appeal decisions; in view of evidence based medicine; the application of Regulations 15(H)(c) and 15l(c); and because no evidence has been put forward of the scheme rule relied upon by the scheme, EIEVS must be considered as a standard of care for the member's PMB condition.

49. Hence, the Appellant submits that both the First and Second Respondent's decisions pertaining to the Appellant's diagnosed PMB condition, namely aortic valve stenosis, is unjustified. EIEVS is, therefore, in the instance of the Appellant, a PMB entitlement and a PMB level of care because the member fits the patient profile for EIEVS contrary to the views expressed by the CRC.

50. Accordingly, the Appellant asks that the appeal is upheld by the Appeals Committee.

[5] See Appeals Bundle at p 80-93.
[6] See Appeals Bundle at p 63-79.

THE RESPONDENT

51. The Scheme submitted that it operates within the framework of the Act and Regulations, its Rules, as approved and registered by the Registrar of the Council for Medical Schemes ("CMS""). The Scheme is therefore bound by the Scheme Rules in terms of section 32 of the Act; and contractually in terms of the membership agreement and the member's chosen benefit option.

52. The Scheme accepts that the diagnosis which falls under the DTP 309E, defined as "*Diseases and Disorders of the Aortic Valve Nos,*" is a PMB condition and that the treatment thereof is Aortic Valve replacement.

53. The scheme placed on record that in this particular case, the funding of EIEVS is not a Prescribed Minimum Benefit ("PMB") level of care for the following reasons:

    53.1 it is not freely available nor is it a prevailing State practice;
    53.2 EIEVS does not have sufficient evidence-based outcomes;
    53.3 there is no clinical motivation as to why EIEVS would be more clinically appropriate for the member than the other 2 valves which were initially approved by POLMED;
    53.4 alternatively, there is no clinical evidence that harm would befall the Appellant if EIEVS was not approved; and
    53.5 it is unreasonable to expect the full funding of EIEVS by the Scheme because it would be against the interests of the entire membership.

54. The Respondent referred the Appeal Panel to the matter B v Pro Sano[7] wherein it was held that the Scheme's obligation is to fund the equivalent of a standard procedure to replace a valve. In the matter BTL v Discovery Medical Scheme[8], the Appeals Committee held that *"the Appellant's contractual relationship with the Respondent is governed by the rules of the Respondent, and the Respondent is bound to apply its rules to all its Members".* Furthermore, the Committee stated that "*The Appellant is seeking funding for a procedure that is excluded by the Respondent's rules, and the Respondent's refusal to fund this procedure is, therefore, justified."*

[7] Page 4 of the Respondent's Heads of argument.
[8] Page 5 of the Respondent's Heads of argument.

55. Based on the above, per the scheme, EIEVS does not accord with the definition of managed care in the regulations nor is it the most clinically appropriate treatment. Therefore the scheme is not obligated to fund EIEVS in full, and where EIEVS is requested, as is the case in this matter, EIEVS can only be funded up to the value of a TAVI procedure.

56. The Scheme contends that it has met all its contractual obligations to the member in that it funded the Appellants procedure up to the level of a TAVI procedure. It is therefore the scheme's submission that the Scheme has no obligation in law or in contract to fund the EIEVS procedure in full and without a co-payment, because EIEVS it is not PMB level of care.

57. Accordingly, the scheme asks that the appeal be dismissed by the Appeals Committee.

DISCUSSION AND ANALYSIS

58. It is common cause that the Appellant's diagnosis of Aortic Valve Stenosis, is a PMB condition listed under DTP 309E "*diseases and disorders of the aortic valve nos"* with the legislated treatment component cited as aortic valve replacement. It is undisputed that the Appellant suffers from severe aortic valve stenosis and ischemic heart disease as well as hypertension and chronic venous insufficiency.

59. In his letter dated 21 June 2021, Dr B, the member's Cardiothoracic Surgeon, recommended EIEVS, citing the member's medical condition and co-morbidities because EIEVS "*will specifically reduce by-pass time."*[9]

60. In a letter dated 21 May 2021 to the member the scheme referenced an Annexure in the Polmed Benefits and Contribution Guide 2021, to the member's request for authorisation for aortic valve replacement, as follows:
"ANNEXURE
Additional clinical notes and scheme rule information that may affect this authorisation.
CLINICAL TREATMENT NOTES

[9] Page 18/320 Letter of Dr Botha, the Cardiologist dated 21 June 2021.

AORTIC VALVE REPLACEMENT: Funding of an open aortic valve replacement subject to available internal/specific prosthesis benefits. Clinical motivation and explicit scheme funding approval required for percutaneous valve replacement or transcatheter aortic valve implantation (TAVI). Proof of entry onto the SA Heart TAVI registry is required to review a TAVI application. No benefits available for the Perceval Suture-less aortic valve."

61. It is to be noted that in terms of the POLMED General Rules Application of Clinical Protocols And Funding Guidelines, Polmed applies clinical protocols, including "*best practice guidelines*" as well as evidence based medicine principles in its funding decisions.[10]

62. Turning to the funding of PMB conditions as outlined in Regulation 8(1), it is undisputed that PMB conditions must be funded in full without any co-payment by the member.

63. In the matter before the Appeals Committee, 3 options for authorisation of an aortic valve replacement were sent by the member's Cardiothoracic Surgeon to the scheme. The scheme communicated to the member that it approved two of the options and declined EIEVS.

64. The main reason advanced by the scheme to the member, amongst other reasons, for declining EIEVS is that it is not a PMB level of care. This is where the parties differ in that the Appellant argues that EIEVS is a PMB level of care and must be paid for "*in full*" by the scheme.

65. The aforementioned is the main issue to be determined by the Appeals Committee.

66. In considering whether EIEVS is a PMB level of care, section 29(1)(o) and regulation 8 must however be read with the contractual obligations between the parties referred to in paragraph 60 above and further read with section 32 of the Act which stipulates that "*The rules of a medical scheme and any amendment thereof shall be binding on the medical scheme concerned, its members, officers and on any person who claims any benefit under the rules or whose claim is derived from a person so claiming."* The Appellant is therefore bound by the Scheme Rules; subject to the members chosen benefit option**.**

67. Regulation 8(1) of the Act compels the Scheme to pay in full without co-payment or the use of deductibles, for the diagnosis, treatment and care costs of the member.

[10] Page 109/320 – Bundle A.

68. The Appellant argued that Regulation 8 stipulates that schemes are provided with two tools to be exercised in line with the Act read with the applicable regulations for –

    68.1 managed care to be exercised as is prescribed in regulations 15A to 15K); and
    68.2 designated service providers, to manage the costs associated with payment "*in full."*[11]

69. Regulation 15 defines "*evidence-based medicine" as the "conscientious explicit and judicious use of the current best medicine in making decisions about the care of beneficiaries whereby individual clinical experience is integrated with the best available external clinical evidence from systematic research".*

70. Regulation 15H(c) of the Act states that: "*provision must be made for appropriate exceptions where a protocol has been ineffective, or causes or would cause harm to a beneficiary, without penalty to that beneficiary."*

71. Regulation 15I(c) of the Act also provides for instances where it would be justified to deviate from the list of medications on a Scheme's formulary if such formulary medicines are, inter alia, ineffective, cause or would cause harm to the member.

72. The Respondent argued that –
    EIEVS in this case is not considered as PMB level of care because (i) it is not prevailing state practice; (ii) does not have sufficient evidence-based outcomes; (iii) there is no clinical indications or motivations as to why EIEVS would be more clinically appropriate instead of the other 2 valves which were approved by POLMED, as requested by the medical doctor in the initial pre-authorisation requests; and (iv) without the necessary clinical evidence that this was the only valve for the condition of the Appellant; alternatively, evidence that harm would befall the Appellant if EIEVS is not approved by the Respondent.[12]

73. The Appeals Committee carefully weighed the evidence of both parties.

[11] Regulation 8 of the Act.
[12] Page 3/7 of the Respondent's Heads.

74. The Appeals Committee also further considered the provision of Explanatory Note 2 to the PMB conditions which states that:

"Where the treatment component of a category in Annexure A is stated in general terms (i.e."medical management" or "surgical management"), it should be interpreted as referring to prevailing hospital-based medical or surgical diagnostic and treatment practice for the specified condition. Where significant differences exist between Public and Private sector practices, the interpretation of the Prescribed Minimum Benefits should follow the predominant Public Hospital practice, as outlined in the relevant provincial or national public hospital clinical protocols, where these exist. Where clinical protocols do not exist, disputes should be settled by consultation with provincial health authorities to ascertain prevailing practice…"

75. The Appeals Committee notes that no clinical or other information was provided to the scheme at the time of seeking pre-authorisation or at the hearing of the matter; or that the use of the other two approved options by the scheme would cause harm to the member; or be ineffective to justify an exception.

76. There is further no evidence before the Appeals Committee that there is more value in EIEVS. In our view, no basis has been laid by the Appellant for the preferred use of EIEVS in this case or that there was an emergency situation. In casu, there is no evidence submitted by the Appellant to support the prevailing use of EIEVS in Public Hospitals when aortic valve replacement is required.

77. There is thus no compelling evidence led by the Appellant, before the Appeals Committee, that medical schemes are obligated to fund EIEVS in full; and in the alternative where EIEVS is requested, the Appeals Committee is satisfied that it must be funded up to the value of the TAVI procedure. In the latter regard, the scheme complied with their contractual obligation in respect of a PMB condition; and acted within the ambit of section 32 of the Act read with the Regulations.

78. The Scheme engaged their clinical advisory committee, and it was advised that there was a lack of robust evidence regarding the funding of suture-less aortic valve replacements, and for that reason, amongst others, the funding of the Perceval Suture-less and Intuity Elite Valve System is not currently supported. Similarly, the CMS Clinical Review Committee of the CMS advised that EIEVS is not PMB level of care.

79. In this matter it must be noted that there is no proof of entry to the TAVI registry; the Appellant has also not disputed that there are no benefits available for the Perceval Suture-less aortic valve; it is undisputed that the Appellant went ahead with the EIEVS procedure in the full knowledge that it was not authorised by the Respondent as required in terms of the members contract with the scheme requiring pre-authorisation of a procedure; and after being made aware in writing that a co-payment would be applicable should the member elect the EIEVS option.

80. Moreover, the Appellants did not lay the basis for EIEVS as the preferred option over and above the two (2) options authorised by the scheme.

FINDING

80. The Appeals Committee is satisfied and finds that:

80.1 the Appellant has not discharged its onus that EIEVS is a PMB level of care and that at the time of the Appellant's treatment, EIEVS was the only surgical management option available for the member's PMB condition.

80.2 after considering the submissions of both parties, including the case law cited by the parties, the Appeals Committee finds that on this set of facts that EIEVS is not a PMB level of care.

80.3 EIEVS is not available in Public hospitals and therefore not a PMB level of care; and

80.4 the Scheme correctly funded the member's PMB condition in terms of the Act, read with the Regulations and the scheme rules pertaining to the member's benefits.

ORDER

81. Accordingly, the Appeals Committee, after careful consideration, makes the following order:

81.1. The Appeal is dismissed.

81.2 The Registrar's decision is upheld.

81.3. There is no order as to costs.

THUS DONE AND SIGNED AT JOHANNESBURG ON THIS THE 19h DAY OF JUNE 2024.

PA BECK
MEMBER APPEALS COMMITTEE

Dr. X. Ngobese, Ms. M. Ramagaka, Dr. K.S. Chetty and Dr. S. Naidoo concur.