BEFORE THE APPEAL BOARD OF THE COUNCIL FOR MEDICAL SCHEMES

In the matter between:

DISCOVERY HEALTH MEDICAL SCHEME	APPELLANT
and	
MR C	FIRST RESPONDENT
REGISTAR FOR MEDICAL SCHEMES	SECOND RESPONDENT
APPEALS COMMITTEE	THIRD RESPONDENT
DATE OF APPEAL HEARING	28 NOVEMBER 2019
	MATTER NO 63935

DECISION

Introduction and Background

1. This is an appeal lodged by Discovery Health Medical Scheme ("Discovery") in terms of section 50(3) of the Medical Schemes Act 131 of 1998 ("the Act") against the ruling of the Appeals Committee of the Council for Medical Schemes ("CMS").
2. The matter arose from Discovery's refusal on or about 20 March 2017 to authorise funding of Xen 45 Glaucoma surgical treatment system ("XEN-stent") that was requested by the first respondent ("Mr C ") who is suffering from primary open-angle glaucoma ("glaucoma").

3. Mr C was referred to Dr Conradie, a specialist ophthalmologist, in 2015 for uncontrolled glaucoma in his right eye. Dr Conradie's letter motivating for the funding of the XEN-stent for Mr C dated 15 March 2017 dwelt on the severity of the condition, describing, *"Mr. C is a patient with severe ocular surface disease, and he is on extensive immune suppressants to control this. He already has a lot of corneal scarring. At that stage he already had bilateral Express valves implanted; the left eye looked good, but the right eye's pressure has started going up and there was no good bleb formation".*
4. When exploring the eye in November 2015, Dr Conradie found that the valve lumen had blocked. Attempts at unblocking the lumen failed, resulting in the removal of the valve and replacing it with the new one, which worked well only for a year. In December 2016 the pressure started going up again.
5. The report went on stating that, *"As we know very well there is scar formation under the bleb of these valves and this blocks the valve outlet so that it cannot drain anymore. This is more common with people with chronic conjunctival inflammation as is the case with Mr. C . I needled that valve and removed some of the scar tissue at the tip, and the pressure came down adequately after I did needling"*
6. At the beginning of March 2017, Mr. C presented again with high pressure in that eye, and again with scarring over the tip of the valve. It was at this stage that Dr Conradie came up with another surgical treatment approach in the form of a different valve that would not require cutting and scleral incision that could potentially scar over. The valve, called XEN-stent, would be placed from the inside of the eye, and would not require any stitching at the wound site. She stated that XEN-stent had recently been launched in South Africa, and her results had so far been good.

7. Dr Conradie's motivation letter to Discovery for funding of the XEN-stent ended by stating that *"Mr. C's pressure is 25mmHg in the eye at the moment and he is losing vision day-by-day when his pressure stays high. He is on glaucoma drops. The only one he can tolerate is Alphagan Purite as all other eye drops available in South Africa has preservatives in them that make his corneal surface disease flare up terrible.*

   I would therefore like to motivate for a Xen-stent for Mr. C . This is an exceptional case, and we do not have any other option". (Emphasis added). Mr C felt aggrieved by the refusal of Discovery to fund the XEN-stent and complained to the Registrar.

8. Defending its decision not to fund the XEN-stent Discovery held that, *"Mr C 's condition, primary open-angle glaucoma is a PMB condition under provision 407B Primary open angle glaucoma with failed medical management and the treatment to be funded is Trabeculectomy; other surgery. Although the funding provision states 'other surgery', the insertion of Xen45 Glaucoma treatment system is not PMB level of care and therefore cannot be funded as such".*

9. The Registrar ruled in favour of Discovery, thereby prompting Mr C to escalate the matter to the Appeals Committee in terms of Section 48 of the Act.

10. The ruling of the Appeals Committee dated 13 March 2019 found that Discovery and the Registrar failed to present adequate grounds for the dismissal of the request by Mr C , that Mr C succeeded in presenting adequate grounds for the upholding of his **claim**, and that there was no justification as to why Discovery could not fund the XEN-stent in full.

11. The Appeals Committee ordered that Discovery should, within 14 days of the ruling, fund the Xen-stent in full, retrospectively from the date that it declined the request by Mr C . That outcome is the subject of this appeal by Discovery to the Appeal Board.

Grounds for the Appeal by Discovery

12. The grounds for the appeal by Discovery are stated as follows:

12.1 That the Appeals committee materially misconstrued the Act and Annexure A of the Regulations by disregarding that the XEN-stent was not predominantly used by state institutions. According to Annexure A the prescribed treatment for primary open-angle glaucoma with failed medical treatment is stated as *"Trabeculectomy; Other Surgery".* It is common cause that XEN-stent is not Trabeculectomy. What needed to be determined was whether XEN-stent fell within the ambit of *"other surgery"*.

12.2 That for the XEN-stent to be regarded as PMB level of care it must fall within the ambit of *"Other Surgery"*. In this regard Discovery made reference to the explanatory notes and definitions, specifically Note (2) of Annexure A of the Act, which provide that where treatment component of a condition 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 exists. Where clinical protocols do not exist, disputes should be settled by consultation with provincial health authorities to ascertain prevailing practice"* In this regard Discovery says that XEN-stent is not predominantly used in state hospitals, thus cannot fall within the ambit of "Other Surgery" and therefore does not constitute a PMB level of care for glaucoma.

12.3 That the Appeals Committee wrongly held that Discovery rules that provide for a General Scheme Exclusion for health care services relating to *"experimental, unproven or unregistered treatment"* were not applicable in this case because XEN-stent was not experimental, unproven or unregistered treatment. The argument by Appeals Committee that, because the treatment had worked on Mr. C , it could not be considered as experimental, unproven or unregistered is unsustainable.

In terms of the rules of Discovery, health care services relating to experimental, unproven or unregistered treatment fall under a General Scheme Exclusion. From Discovery point of view, XEN-stent is considered as experimental, unproven or unregistered treatment.

12.4 *That "the Appeals Committee also relied on Regulation 15H(c) as a basis for holding that DHMS ought to have authorised the XEN 45 treatment system…..Regulation 15H is not applicable".*

13. That Discovery was entitled to decline funding for XEN-stent because, (i) the device is not PBM level of treatment for primary open-angle glaucoma with failed medical management, (ii) according to the rules of Discovery, healthcare services relating to experimental, unproven, and unregistered treatment will not be paid for, and, (iii) at the time authorisation was declined, the XEN-stent was experimental, unproven, or unregistered.

Merits of the Appeal

14. It is common cause that glaucoma is a PMB condition.

15. It is undisputed that Mr C is suffering from severe and complicated glaucoma with severe ocular surface disease, is on extensive immune suppressants, and already has a lot of corneal scarring that resulted from the previous surgical interventions. When he was referred to the eye specialist, Dr Conradie, in 2015 he already had bilateral Express valves implanted; the left eye looked good, but the right eye's pressure had started going up and there was no good bleb formation. On exploration in November 2015, the valve lumen was found to have blocked. Having failed to unblock the valve, a new valve was inserted, and it worked only for a year, after which the scarring, lumen blocking and increasing intraocular pressure ("IOP") recurred.

16. It became necessary for Dr Conradie to look at different treatment approach in the form of the XEN-stent that would not require cutting, scleral incision and/or stitching. This was the only alternative that would avoid recurrent scaring of the cornea and resultant blocking of the valve lumen. Dr Conradie reported that the results of her patients who had undergone XEN-stent surgery were *"really good"*.

17. In terms of Regulation 15H(c) of the Act "*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".* This Regulation relates to medical schemes that are using managed health care system of which Discovery is one of them.

A protocol is defined in the Act as *"a set of guidelines in relation to the optimal sequence of diagnostic and treatments for specific conditions and includes, but is not limited to, clinical practice guidelines, standard treatment guidelines, disease management guidelines, treatment algorithms and clinical pathways".* (Own emphasis) In line with this definition, an algorithm is a subset or element of a protocol.

18. There is an algorithm (hence a protocol) that is used by Discovery in the management of glaucoma. Taking into account the definition of a protocol, and the provision of Regulation 15H(c) mentioned above, as well as the motivation letter from the treating specialist ophthalmologist, the algorithm (protocol) used by Discovery for the treatment of glaucoma was ineffective, and it caused harm to Mr C 's right eye as illustrated by the fact that he developed recurrent corneal scarring and blocking of the Express valves, leading to further increases in his intraocular pressure ("IOP") and further deterioration of his vision. Any other type of valve or device that would require cutting, scleral incision and/or stitching during implantation would likewise produce an undesirable outcome. In this situation it is incumbent upon the appellant, Discovery, to show the existence of treatment in the state that is effective and not harmful or not potentially harmful to Mr C . It is worth noting that the appellant, Discovery, did not submit any expert opinion disputing Dr Conradie's specialist opinion that Mr C 's condition was severe, and that there was no other option available. Citing from her motivation letter she stated that "*I would therefore like to motivate for a Xen-stent for Mr. C . . This is an exceptional case, and we do not have any other option".* On this basis, Regulation 15H(c) is considered applicable.

19. It is unreasonable that discovery would, on the one hand, decline funding XEN-stent for the treatment of glaucoma, and fail to offer or suggest an alternative effective surgical treatment modality that would not harm Mr C or result in corneal scarring and loss of vision on the other hand. The Clinical Review Committee ("CRC") of the CMS also requested that Discovery should advise Mr C and his doctors about the alternatives that are funded in the light of Mr C 's medical history. That did not happen.

20. Regarding the inquiry on the prevailing treatment practice at state hospitals, as already stated above, Discovery did not dispute that the prevailing practice/level of care in the state hospitals for the treatment of Mr C 's condition was ineffective, harmful or potentially harmful, and there was no other clinically appropriate alternative than the XEN-stent. The argument of prevailing state hospital practice in establishing whether or not a specific treatment constitutes PMB level of care should, in our view, not be applied in a narrow or rather simplistic manner; otherwise it would be open to abuse and incorrect decision making by some medical schemes. There are other factors, other than affordability or cost effectiveness, that may well be the reason for the non-use of a particular treatment by the state hospitals, such as budgetary processes or constraints, delayed bureaucratic tendering/procurement processes, skills shortage, human resource training priorities, administrative challenges, and adverse reaction to the treatment to name a few. In the absence of evidence from Discovery showing the availability of alternative treatment modalities at the state hospitals that would be effective or would not cause harm, the argument on the prevailing state hospital practice would be irrelevant, unreasonable and not be in the best interest of Mr C .

After all, the XEN-stent is cheaper, affordable and effective than any other option as discussed in paragraph 22 below.

21. Without basing our Decision thereon, we mention the following developments post the appellant's refusal to fund the XEN-stent treatment. To some extent though, they may belie the fact that the treatment was experimental.

21.1 Discovery stated that at the time of application for authorisation Discovery was still clinically evaluating the XEN-stent treatment system, and was of the view that it remained *"experimental, unproven or unregistered treatment"*.

In this regard Mr C submitted sufficient evidence dating back to 2016 reporting good efficacy and favourable safety profile of the XEN-stent.

Furthermore, the XEN-stent was approved and cleared for marketing by FDA (Food and Drug Administration in November 2016, and obtained CE Mark approval 597638 in 2012. CE marking is a certification mark or symbol applied to products to indicate that they conform to the relevant European Union directives regarding health, safety and environmental protection standards. CE is the abbreviation for the French phrase *"Conformite Europeene"*, literally meaning *"European Conformity"*.

21.2 The South African Glaucoma Society ("SAGS") in its Policy Statement on Glaucoma of November 2017 endorsed that all devices must be approved by FDA, or CE or both before being allowed to be used in South Africa. SAGS also confirmed that all devices that have been approved by FDA and CE, as is the case with XEN 45, have <u>already undergone multiple trials before being released to surgeons to use; and patient safety and effectiveness of the devise have been tested and confirmed.</u>

An affidavit deposed by Allergan, the supplier of the product, on 26 October 2018 stated that XEN-stent was used in 22 countries, including South Africa, and over 60 000 patients worldwide had received the XEN-stent. Our view therefore is that the XEN-stent is not experimental, unproven or unregistered treatment; and therefore does not constitute General Scheme Exclusion under Annexure C of Discovery's Rules.

22. Going back to Mr C 's argument, he points out that the cost of the XEN-stent was far less than the cost of other devices which were funded Discovery, citing R9 000 as opposed to R20 000; and Discovery did not dispute, or submit evidence to the contrary, and had onus to do so.

As already stated, Discovery is using managed health care system which is defined in Regulation 15 of the Act as *"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 rule-based and clinical management based programmes".* Therefore, the objective or guiding principle of managed health care system is to achieve appropriateness, cost effectiveness and affordability of health care.

The consideration of the importance of affordability and cost effectiveness in the development of a protocol (algorithm) is further stated in Regulation 15H(a) that *"protocol must be developed on the basis of evidence-based medicine, taking into account considerations of cost-effectiveness and affordability".*

It is mind-boggling that Discovery would be willing to fund the inappropriate treatment for R20 000, and refuse to fund an effective, affordable and cost-effective treatment for R9 000. This kind of decision making is viewed as irrational and contrary to the objective of managed health care stated above.

23. Summary and Conclusion

23.1 Discovery failed to advise the first respondent and his doctors on the alternative surgical treatment option that is prevailing in state hospitals, and which would not cause harm to Mr C , i.e. treatment that would not require cutting, scleral incision and stitching, thereby preventing scaring and blocking of valve lumen.

23.2 The algorithm/protocol used by Discovery in treating glaucoma was ineffective, harmful or potentially harmful to Mr C .

23.3 Regulation 15H(c) of the Act on consideration of exception is relevant and applicable.

23.4 The XEN-stent was not experimental, unproven or unregistered treatment; and therefore did not constitute General Scheme Exclusion under Annexure C of Discovery's Rules.

23.5 The XEN-stent is cheaper, affordable and clinically effective, and not harmful to Mr C . The decision by Discovery not to fund the XEN-stent at all but instead be willing to fund an ineffective, potentially harmful and more expensive device, is irrational and is defying the principles and objectives of managed health care system.

23.6 For the reasons stated in paragraphs 23.4 and 23.5 above, the argument on prevailing state hospital practice is irreverent and not applicable.

Against this background, we conclude that XEN-stent must be considered PMB level of care for the treatment of Mr C 's primary open-angle glaucoma that did not respond to medical management.

24. For the reasons stated above this appeal must fail, and the following order is made:

    24.1 The appeal is dismissed.

    24.2 The Ruling of the Appeals Committee is upheld.

    24.3 Appellant is ordered to fund the XEN-stent in full for the treatment of Mr C 's condition in question.

Dated this 27th day of January 2020

Judge B M Ngoepe, Chair, Appeal Board

Dr N B Jada, Member, Appeal Board

Dr D Ramagole, Member, Appeal Board