BEFORE THE APPEAL COMMITTEE OF THE COUNCIL FOR MEDICAL SCHEMES (SECTION 48 APPEAL)

HELD VIA MICROSOFT TEAMS VIDEO AND AUDIO-CONFERENCING TECHNOLOGY.

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

In the matter between	**Ref number: CMS 81498**
Medihelp Medical Scheme	**Appellant**
And	
The Registrar of Medical Schemes	**First Respondent**
Ms J	**Second Respondent**

Panel: Dr K. Chetty; Dr X. Ngobese; Ms P. Beck; Dr S Naidoo.

Date of hearing: 2 December 2024.

Date of ruling: 22 January 2025.

RULING AND REASONS

THE PARTIES

1. The Appellant is Medihelp Medical Scheme (The "Appellant or the "Scheme"), registered and regulated under the Medical Schemes Act, Act 131 of 1998 (the "MSA" or "Act").
2. Ms T, Legal Advisor for Medihelp appeared for the Appellant.
3. The First Respondent is the Registrar of the Council for Medical Schemes. The First Respondent did not appear at the hearing but indicated that the Registrar would abide by the Appeals Committee Decision.
4. The Second Respondent is Ms. J (The "Second Respondent" or "Member"), a member of Medihelp Medical Scheme.

BACKGROUND

5. The Second Respondent, Ms J is a member of the Medihelp medical scheme, on the MedSaver benefit option.
6. Ms J has been diagnosed with rheumatoid arthritis, which is classified M06.99 and registered the condition for Prescribed Minimum Benefits (PMB) with Medihelp. She subsequently developed Psoriatic Arthritis and Spondylarthritis.
7. She has been treated with the following medication; Methotrexate, Lyrica, Cymge, Tripilin, Plasmaquine, Rheumaleve, Celebrex, Palexia and Mypocame which have not been effective.
8. The 2nd Respondent's rheumatologist prescribed Humira (Adalimumab) 20 milligrams, which is a biologic medication.
9. The Scheme stated that "*the PMB treatment algorithm for the condition rheumatoid arthritis does not include Humira (adalimumab) as a treatment option and Medihelp therefore declined funding for Humira as PMB medicine."*
10. The Scheme indicated, in addition, that Humira is classified as a biological and since biological therapy is excluded from benefits on Mrs. J benefit option. The member will be liable for payment of the accounts for Humira.

11. Mrs J self-funded two treatments with Humira, but due to an adverse event treatment was stopped. The Member, however, requests the Scheme to fund the two doses of Humira that she self-funded.
12. The Scheme concluded that the Registrar erred in its decisions that Humira constitutes PMB level of care and that there is no legal basis to compel the scheme to fund this treatment which is not within the benefits entitlement.

THE REGISTRAR'S RULING

13. The Registrar's Ruling was issued on 14th March 2023.
14. The Registrar ruled that based on the Clinical Review Committee (CRC) report that because the complainant failed treatment with medicines on the PMB treatment algorithm, Humira is therefore PMB level of care for the complainant's condition and confirmed that Regulation 15(H)(c) applies in this case.
15. The Registrar found that the complainant's two boxes of Humira must be funded in full as PMB level of care for her condition.
16. The Appellant is now appealing this decision of the Registrar in terms of Section 48 Appeal submitted on 29th May 2023.

APPLICATION TYPE AND RELIEF SOUGHT

17. This is an appeal under section 48(1) of the Medical Schemes Act (the "MSA or the Act").[1] This section provides that:
    a. *"(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".*
18. The Appeals Committee heard the appeal on 2nd December 2024 via an audio and video conferencing link.
19. This hearing concerns the merits of the appeal filed.

RELEVANT STATUTORY AND REGULATORY PROVISIONS

20. The relationship between the Scheme and the Second Respondent is governed by the terms of the contract ("the schemes rules") the Scheme concluded with the Second

[1] Medical Schemes Act 131 of 1998 as amended by Act 55 of 2001; Section 48(1); Proc 13/GG 19725/19990129

Respondent. The contract in turn is governed by the "MSA" and the regulations (as amended) made in terms of the Act.

21. This is a wide appeal. The Appeals Committee may consider the matter afresh and is not restricted to the record of proceedings that were before the Registrar.
22. 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

23. The issue in dispute is whether the scheme was correct to not fund Humira for the PMB condition of Rheumatoid Arthritis.

APPELLANTS SUBMISSION

24. The Appellant states that Mr. J and his dependants are enrolled on the MedSaver benefit option, which covers approved prescribed minimum benefits (PMB) chronic medicine in line with the PMB treatment algorithm for the applicable conditions. Mrs J was diagnosed with Rheumatoid Arthritis and the Scheme acknowledges that this is a PMB condition.
25. On 1st November 2022 the Scheme received a motivation letter from Mrs. J's treating physician, Dr R, for funding of the drug known as Humira (Adalimumab) as a treatment option.
26. The scheme communicated to Mrs. J that the request to fund the medicine was declined because biological therapy is excluded in terms of the Rules of the scheme (paragraph 7.3.4 of Schedule C to the Rules of Medihelp all biological/biosimilar pharmaceuticals are excluded from the benefits) and is not regarded as PMB level of care for Mrs J's condition.
27. The Appellant concedes that Ms J requires medical management of her condition and that her condition is a PMB condition. However, the scheme is of the opinion that the chronic use of a biological does not fall within the ambit of PMB entitlement for this condition and furthermore takes issue with the application of Regulation 15H in this matter.
28. The Appellant avers that Section 29(1)(o) and 29(1)(p) of the Act afford the scheme a discretion as to the benefits it wishes to afford to its members and if the scheme does not grant benefits in full, payment of the service remains for the member.

29. The Appellant states that Regulation 8 is subject to Section 29(1)(p) of the Act which stipulates that no limitation shall apply to the reimbursement of any relevant health service obtained by a member from a public hospital where this service complies with the general scope and level as contemplated in paragraph (o) and may not be different from the entitlement in terms of the service available to a public hospital patient.
30. The appellant argues that to better determine what the PMB entitlement should be for this condition in the Diagnosis and Treatment Pair (DTP) and to establish the extent of the PMB level of care in this instance the scheme refers to the prevailing practice in state hospitals as per the explanatory note 2 outlined below:[2]

> *"Explanatory Note 2 of Annexure A of the Act advises 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 specific condition. Where significant differences exist between Public and Private sector practice, the interpretation of the PMB should follow the predominant public hospital practice, as outlined in the relevant provincial and national public hospital clinical protocols where these exist close."*

31. The Appellant argues that Regulation 15 deals with circumstances where managed healthcare interventions are utilised to manage access to benefits. They are in themselves further limitations on accessing benefits and are not designed to extend the benefits.
32. Protocol is defined in Regulation 15 as: "*guidelines and relation to the optimal sequence of diagnostic testing 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."*
33. The Appellant states that "*Regulation 15 only therefore becomes applicable with managed health care interventions which are used in order to manage access to benefits. In denying funding, the Scheme has not used any managed health care interventions, but merely relied on the legislated treatment algorithm as well as its registered rules."*[3]
34. Having regard to the above, the Scheme submits that Regulation 15(H)(c) is therefore not applicable in the circumstances because Regulation 15(H)(c) deals with the use of (internal) protocols which reads as follows:

[2] Page 39 of the pack.
[3] Page 39 of the pack.

15H. 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.

35. The Appellant argues "*if the Scheme imposes managed health care for the access of benefits and in so doing, uses a protocol, then if the protocol has been ineffective or causes harm an exception must be made. In this instance no protocol is used and no manage healthcare is being applied. The PMB treatment algorithms as provided for in the Regulations and duly promulgated are being applied."*[4]
36. The Appellant submits that Regulation 15(H) is not a catch-all tool that overrules Regulation 8.
37. The Scheme submits that having considered all applications for chronic or PMB medicines according to the Act and the PMB treatment algorithms contained in the Regulations published under the Act, to ensure the consistent and fair granting of medicine benefits to all members, that requests for funding of Humira treatment for Rheumatoid Arthritis, does not qualify for benefits in terms of the Rules of Medihelp, and it cannot be compelled to fund the treatment.
38. The Appellant request the Appeals Committee to uphold its decision not to fund the treatment as PMB level of care based on the facts stated above and taking into consideration the impact of approving such funding on the Schemes viability and affordability to members'.
39. The Appellant states that the registrar cannot compel the scheme to fund expenses incurred which is not within the benefit entitlements in respect of this membership at this would be the equivalent of to instruct the Scheme to contravene its own rules which have been approved by the Registrar.

RESPONDENTS SUBMISSION

40. The Second Respondent Ms J is a member of Medihelp on the MedSaver benefit option.
41. The Second Respondent stated that she has been diagnosed with Sero-negative rheumatoid arthritis and later on with Psoriatric Arthritis and Spondylarthritis. She has registered the condition which is classified M06.99 for Prescribed Minimum Benefits (PMB) with Medihelp.

[4] Page 40 of the pack

42. Ms J states that she has been on a number of drugs Methotrexate, Lyrica, Cymge, Tripilin, Plasmaquine, Rheumaleve, Celebrex, Palexia and Mypocame.
43. Her Rheumatologist, Dr R has indicated that she has failed all first line disease modifying anti rheumatic drugs (DMARD) i.e. Methotrexate, Salazopyrine, Plasmaquine and Rheumalef. Dr R has requested Humira medication which she indicated is on the government formulary[5].
44. She says her condition is getting worse with progression in her spine and her Rheumatologist states that she still has a high clinical daily activity index (CDAI) score of a simplified daily activity index (SDAI) total of 26.
45. Mrs J self-funded two treatments with Humira, but due to an adverse event treatment was stopped. The Member, however, requests the Scheme to fund the two doses of Humira that she self-funded.

DISCUSSION AND ANALYSES

The Appeals Committee considered papers filed in this appeal; the further submissions the party's made; the relevant provisions of the Medical Schemes Act; and the Rules of the Scheme.

46. It is common cause that
    a. The Second Respondent has been a member of the Medihelp medical scheme and covered on the MedSaver benefit option.
    b. The member has Sero-negative rheumatoid arthritis, Psoriatric Arthritis and Spondylarthritis, and has been treated with amongst others the following medications: Methotrexate, Salazopyrine, Plasmaquine and Rheumalef.
    c. The treatment has not worked and the treating doctor recommended escalation to Humira, a Biological in November 2022.
    d. The Scheme declined the funding of Humira for Rheumatoid Arthritis stating that it does not qualify for benefits in terms of the Rules of Medihelp and the member's benefit entitlements.
47. From the evidence provided there is no dispute that rheumatoid arthritis, is a PMB and treatment for that should be at the PMB level of care.
48. The Appellant in its Head of Argument states that "*regulation 8 promulgated under the Act states that any benefit option offered by medical scheme must pay in full, without co-payments or the use of deductibles, the diagnosis, treatment and care costs of the*

[5] Page 10 of the bundle

PMB conditions. However, regulation 8 is subject to section 29(1)(p) of the Act which stipulates that no limitation shall apply to the reimbursement of any relevant health service obtained by a member from a public hospital with this service complies with the general scope and level as contemplated in paragraph (o) and may not be different from the entitlement in terms of a service available to a public hospital patient"[6].

49. The Appellant further argues that: "*mindful of the obligation and limitation that section 29(1)(o) of the Act imposes on a medical scheme to ensure its beneficiaries have access to PMB, section 29(1)(q) does afford the scheme a discretion as to the benefits it wishes to afford its members."*
50. This argument is not valid, as from a legal standpoint the Scheme's Rules do not supersede the Act and Regulations. Pearmain DL in her book the Law of Medical Schemes stated: "*Although the Act states that a scheme is bound by its rules, if one or more of those rules is contrary to law, the law will take precedence. The correctness of this statement was confirmed by the Supreme Court of Appeal in Council for Medical Aid Schemes and another v Genesis Medical Scheme and others 2016 (1) SA 429 (SCA) at para 43."*[7]
51. The Scheme further argues that *Regulation 15 only therefore becomes applicable where managed healthcare interventions are used in order to manage access to benefits. In denying funding the scheme has not used any managed healthcare interventions but merely relied on the legislated treatment algorithm as well as its registered rules."*
52. The Appellant also quoted Explanatory Note 2 of Annexure A of the Act and confirmed the interpretation of the PMB should follow the predominant public hospital practice.
53. The Appellant having used this argument did not provide any proof of predominant public hospital practice.
54. In the National Department of Health Tertiary and Quaternary Level Essential Medicines List it is clearly stated that *"Rituximab is approved for patients with Refractory Rheumatoid Arthritis (RA) who have failed 3 or more DMARDS taken for more than 6 months (in accordance with the algorithm)."*[8] The EML therefore recommends Rituximab, a biological as part of the treatment algorithm for Rheumatoid Arthritis not responding to DMARDs.
55. Regulation 15H Protocols by definition states:

> **"protocol"** means a set of guidelines in relation to the optimal sequence of

[6] Page 39 of the pack
[7] Pearmain DL: The Law of Medical Schemes in South Africa. Juta May 2023
[8] "Page 24 of the pack.

> diagnostic testing 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.

56. The scheme's treatment algorithms (which is a protocol) must make provision for Regulation 15(H)(c) where 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.
57. In this instance the member has failed all first line DMARD, which have been ineffective.

FINDING

58. The members condition, Rheumatoid Arthritis is a Prescribed Minimum Benefit (PMB).
59. The member has failed all first line DMARDs which have been ineffective.
60. The predominant public sector hospital practice through the NDoH EML recommended the use of biologicals where DMARDs have been ineffective.
61. Accordingly, the Appeal Committee is of the view that as the member has failed treatment on synthetic DMARDS on the PMB treatment algorithm, Humira (or an alternative biologic DMARD) is therefore PMB level of care for the member's condition.

ORDER

Having considered the matter the Appeals Committee orders that:

b. The appeal is dismissed.
c. The decision of the registrar is upheld.
d. There is no order to costs.

Dated at Johannesburg on 22 January 2025

Dr KS Chetty (For and on behalf of the Appeals Committee)

Concurring:

Dr X. Ngobese, Ms P. Beck, Dr S Naidoo.