

**THE COUNCIL FOR MEDICAL SCHEMES  
APPEAL COMMITTEE**

In the Appeal between:

**Dr. Traub**

Appellant

and

**DISCOVERY HEALTH MEDICAL SCHEME**

Respondent

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**APPEAL RULING**

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1. The Appellant, Dr B Traub, as a medical practitioner, specialising in rheumatoid arthritis. Dr Traub brings this appeal on behalf of her patient, E.
  
2. E has been a dependant member of the Respondent since 1996. She is 52 years old and has suffered from rheumatoid arthritis for the last 25 years.
  
3. It is common cause between the parties that treatment of E's condition using non-steroidal anti-inflammatory agents ("NSAIDs") and 'traditional' or 'conventional' disease modifying

antirheumatic drugs ("DMARDs") has failed. What is meant by 'traditional' or 'conventional' DMARDs is discussed later in this ruling.

4. As a result of this, Dr Traub has prescribed the use of a biologic TNF-antagonist drug, the trade name of which is Enbrel (these drugs are also referred to as 'anti-TNF' drugs, as is discussed below).
5. It is common cause that Enbrel is the appropriate drug for the treatment of E's condition. It may be noted that treatment using a different biologic TNF-antagonist, Revellex, has been tried, but has been unsuccessful.
6. It is further common cause that the Respondent funded E's use of Enbrel in full for the three-year period to December 2006. However, with effect from January 2007, and in accordance with a funding protocol developed and implemented by the Respondent, the Respondent imposed a 20% co-payment and a R100 000.00 annual limit on members using Enbrel. According to this funding protocol the Respondent continued to fund the

use of two other biologic TNF-antagonist drugs, Revellex and Humira, in full, with no co-payment by the member.

7. The question that arises for decision by the Appeal Committee is whether or not the co-payment imposed by the Respondent in accordance with its funding protocol with regard to Enbrel is in accordance with the Medical Scheme's Act, 131 of 1998 and the regulations promulgated thereunder.
8. The starting point for this analysis is the recognition that rheumatoid arthritis is a chronic prescribed minimum benefit ("PMB") condition as defined in the Chronic Conditions listed in Annexure "A" to the regulations in terms of the Medical Schemes Act.
9. Regulation 8 of the regulations concerns prescribed minimum benefits. It provides as follows:

*"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."*

10. The determination of this appeal depends on the meaning to be attributed to the word "treatment" in the above regulation.
11. Annexure "A" to the regulations, to which reference has been made above, contains a list of acute and chronic PMB conditions, and also prescribes the required treatment in respect of each of these conditions.
12. In respect of the number of the acute conditions included in Annexure "A", the prescribed treatment is listed as "medical management", "surgical management" or "medical and surgical management". According to note 2 to Annexure "A", where these general terms are used - *"it should be interpreted as referring to prevailing hospital-based medical or surgical diagnostic and treatment practice for the specified condition"*
13. However, with regard to the chronic PMB conditions, the prescribed treatment is not recorded in general terms. Instead the treatment is described as follows –

*"Diagnosis, medical management and medication, to the extent that this is provided for by way of a therapeutic algorithm for the specified condition, published by the Minister by notice in the Gazette".*

14. The affect of the foregoing is as follows:
  - 14.1. regulation 8 obliges schemes to provide treatment for the PMB conditions without co-payment or deduction;
  - 14.2. the 'treatment' to which reference is made in regulation 8 is the treatment that is specified in annexure "A" to the regulations;
  - 14.3. where that treatment is stated in general terms, as discussed above, reference must be had to the prevailing medical or surgical practice for that condition. (It may be noted that where there is a discrepancy between public and private sector practice, the predominant public sector practice will prevail in terms of note 2 to annexure "A");

- 14.4. where, in annexure "A", treatment is not described in general terms, the extent of the obligation of the scheme will be defined by the description of the treatment included in annexure "A";
- 14.5. in the case of chronic PMB conditions, the extent of a scheme's obligation will be defined by the published therapeutic algorithm for that condition.
15. On 6 October 2003, the Minister of Health issued therapeutic algorithms for chronic conditions (Government Notice R1402 published in Government Gazette 25537 of 6 October 2003). The introduction to those therapeutic algorithms records that they are the "therapeutic algorithms referred to in annexure "A" to the regulations".
16. The therapeutic algorithm for rheumatoid arthritis prescribes the use of non-drug measures together with NSAIDs. This is followed by the use of DMARDs together, where necessary, with Corticosteroids. This treatment is to be continued if successful,

and reviewed if not. The scheme, in the latter instance, is required to consider other DMARD therapies.

17. The notes to the therapeutic algorithm for rheumatoid arthritis are of some significance. They provide as follows:

*"Note –*

- 1. Medical management reasonably necessary for the delivery of treatment described in this algorithm is included within this benefit, subject to the application of managed health care interventions by the relevant medical scheme.*
- 2. To the extent that a medical scheme applies managed health care interventions in respect of this benefit, for example, clinical protocols for diagnostic procedures or medical management, such interventions must –*
  - (a) not be inconsistent with this algorithm;*
  - (b) be developed on the basis of evidence-based medicine, taking into account considerations of cost-effectiveness and affordability, and*

*(c) comply with all other applicable regulations made in terms of the Medical Schemes Act, 131 of 1998.*

*3. This algorithm may not necessarily always be clinically appropriate for the treatment of children. If this is the case, alternative paediatric clinical management is included within this benefit, if it is supported by evidence-based medicine, taking into account considerations of cost-effectiveness and affordability.”*

18. The Appellant has urged the Appeal Committee to interpret Note 2(c) above, as having the effect of preventing medical schemes from developing protocols for the treatment of rheumatoid arthritis that either preclude the use of TNF-antagonist drugs or require some co-payment in respect of their use.
19. The Appellant argues that if a protocol is developed that has this effect (as is the case in the current dispute, where the funding protocol developed by the Respondent requires co-payment in respect of Enbrel) then the protocol conflicts both with regulation 8 and with regulations 15H and/or 15I.

20. In order to assess whether the requirement of co-funding in respect of Enbrel is in conflict with the regulations, it is necessary to understand the nature of TNF-antagonist drugs and their relationship to 'traditional' or 'conventional' DMARDs. According to a recent article published in the journal of rheumatology of the Asia Pacific League of Associations for Rheumatology<sup>1</sup>:

*"anti-tumour necrosis factor-[alpha](anti-TNF-[alpha]) agents are biologic disease-modifying anti-rheumatic drugs (DMARDs) used in the treatment of moderate to severe rheumatoid arthritis (RA)".*

21. TNF-antagonist drugs form part of a new category of medication generally referred to as biological response modifiers (BRMs). In the case of rheumatoid arthritis the medical function of these BRMs is described on the website of the Arthritis Society of Canada in the following terms:

*"The BRMs are designed to target specific components of the body's immune system, called cytokines, which contribute to the disease process of rheumatoid arthritis. By neutralising or*

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<sup>1</sup> "The use of anti-tumor necrosis factor-[alpha] therapies for rheumatoid arthritis in Singapore" APLAR Journal of Rheumatology, August 2006, by Thong, Vasoo & Koh.

*'soaking up' these targeted cytokines, BRMs play a role in reducing the symptoms of rheumatoid arthritis and decreasing the inflammation that can cause joint deformity".*

22. The inclusion of a drug in the category known as DMARDs must depend on whether or not that drug works by altering the immune system function to halt the underlying processes that cause certain forms of inflammatory arthritis<sup>2</sup>.

23. The website of the Arthritis Health Centre (Cleveland Clinic) records as follows;

*"Over the past several years, researchers have developed newer DMARDs that more specifically target the immune system and have fewer side effects. These are called Biological Response Modifiers or Biologics. They include: Enbrel, Humira, Kineret and Remicade".*

24. The significance of the above quotation is the inclusion of TNF-antagonist drugs in the general category of drugs known as DMARDs. The characterisation of these biologics as falling

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<sup>2</sup> This description is provided by the Arthritis Health Centre of the Cleveland Clinic.

within DMARDs is one that would appear to be common. By way of illustration:

24.1. Dr K Donahue of the University of North Carolina has conducted a study to identify differences in the efficacy or safety between "conventional" or "synthetic" DMARDs on the one hand and "biologic" DMARDs on the other, the latter category consisting of anti-TNF biologics<sup>3</sup>;

24.2. researchers at the Harvard Medical School's Brigham and Women's Hospital conducted a study to compare the cancer risks associated with "biologic DMARD therapy" as compared to "standard prescription DMARDs"<sup>4</sup>

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<sup>3</sup> Referred to in an article entitled "Methotrexate plus Anti-TNF drugs wins plaudits in RA", by J Gever ([www.medpagetoday.com/rheumatology/arthritis](http://www.medpagetoday.com/rheumatology/arthritis)).

<sup>4</sup> Referred to in an article entitled "*No Increased Risk Of Lymphoma Or Tumors Associated With Anti-TNF Therapy Over Methotrexate Use Among Rheumatoid Arthritis Patients, Study Finds*". ([www.medicalnewstoday.com](http://www.medicalnewstoday.com)),

- 24.3. Conventional DMARD drugs were described as "non-biological DMARDs" in an article by Austrian researchers published in August 2007<sup>5</sup>;
- 24.4. the guidelines of the American College of Rheumatology refer to the use of either "traditional or biologic DMARDs"<sup>6</sup>;
- 24.5. In an article published on the website of the National Rheumatoid Arthritis Society of the United Kingdom on 25 April 2006 Dr Raashid Luqmani set out a table of available DMARD therapies and included Etanercept (Enbrel), Infliximab and Adalimumab in his list of DMARDS, all of which are biologic anti-TNF drugs<sup>7</sup>
25. The importance of the above exercise lies in determining whether TNF-antagonist drugs fall within the scope of the therapeutic algorithm for the treatment of rheumatoid arthritis.

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<sup>5</sup> The Annals of Rheumatic Diseases 2007; 66: 1059 – 1065

<sup>6</sup> [www.ra.com](http://www.ra.com)

<sup>7</sup> [www.rheumatoid.org.uk](http://www.rheumatoid.org.uk)

26. That algorithm, as has been seen above, obliges schemes faced with the failure of first choice or frontline DMARDs to review their treatment and "consider other DMARD therapies". In the view of the committee - accepting that TNF-antagonist drugs are biologic DMARDs as distinct from conventional, traditional or synthetic DMARDs - in circumstances where treatment with conventional DMARDs fails, a scheme would be obliged in terms of the algorithm to consider biologic DMARD therapies.
27. There can be no question that the Respondent, in developing a funding protocol, is acting within its rights. The use of such protocol or of a formulary is specifically recognised in regulation 8, regulations 15H and I and in the note to the therapeutic algorithm for the treatment of rheumatoid arthritis.
28. Regulation 8(5) provides as follows:

*"when a formulary includes a drug that is clinically appropriate and effective for the treatment of a prescribed minimum benefit condition suffered by a beneficiary, and that beneficiary knowingly declines the formulary drug and opts to*

*use another drug instead, the scheme may impose a co-payment on the relevant member".*

29. By implication the above regulation confirms that no co-payment may be imposed other than where a beneficiary declines the use of an appropriate drug for the treatment of a PMB condition.
30. Regulations 15H and 15I are more direct. They regulate the use of protocols and formularies and place an obligation on the Scheme to make provision for:
  - 30.1. appropriate exceptions where a protocol has been ineffective or causes or would cause harm to a beneficiary, without penalty to the beneficiary (in the case of regulation 15H); and
  - 30.2. appropriate substitution of drugs where a formulary drug has been ineffective or causes or would cause adverse reaction in the beneficiary, without penalty to that beneficiary (Regulation 15I)
31. These provisions tie in with Note 2 to the therapeutic algorithm referred to above, which requires that any managed healthcare

interventions applied by a scheme must not be inconsistent with the algorithm and must comply with all other applicable regulations in terms of the Act.

32. The Respondent has raised the issue of cost-effectiveness as a fact to excusing it from its obligation to provide Enbrel to E without co-payment. It argues that it has developed a funding protocol on the basis of evidence-based medicine taking into account considerations of cost-effectiveness and affordability, as envisaged in Regulation 15H(a).
33. It is correct that Regulations 15H and 15I place an obligation on a scheme that uses either a protocol, a formulary or a restricted list of drugs, to develop such protocol or formulary on the basis of evidence-based medicine, taking into account considerations of cost-effectiveness and affordability.
34. What this requires, therefore, is that there be a rational, justifiable basis for the protocol or the formulary as a whole. This requirement does not and cannot excuse the scheme from its obligations in terms of section 15H(c) and 15I(c), both of which specifically provide that provision must be made for departures

from the protocol or formulary where necessary without penalty to the beneficiary.

35. The Respondent's funding protocol requires a co-payment by E in respect of the use of Enbrel. It has been accepted by the scheme that its formulary drugs have been ineffective or cause or will cause an adverse reaction in E. Regardless of the basis upon which the scheme developed and derived at its formulary, it cannot advance that formulary as a basis to impose a penalty in the form of a co-payment on E.

36. My conclusions may therefore be summarised as follows:

36.1. rheumatoid arthritis is a chronic PMB condition;

36.2. regulation 8 requires schemes to afford treatments to their members for PMB conditions without co-payment;

36.3. the treatment which schemes are obliged to provide in respect of rheumatoid arthritis is the treatment set out in the therapeutic algorithm published in terms of the Act;

- 36.4. that algorithm requires the consideration, where appropriate, of all available DMARD therapies;
  - 36.5. schemes are therefore obliged in terms of the therapeutic algorithm to consider (and by implication provide where appropriate) TNF-antagonistic drugs.
  - 36.6. the effect of regulation 8, regulations 15H and 15I, and the notes to the therapeutic algorithm, is that although a scheme may develop a formulary, where departure from that formulary is necessary for the treatment of a particular member, such departure must be accommodated with no penalty (in the form of co-payment or deduction) to the member.
37. In the circumstances the imposition of the co-payment of 20% and of an annual limit of R100 000.00 on the use of Enbrel on E contravenes the Medical Schemes Act and the regulations thereunder. The appeal is accordingly upheld and the scheme is ordered to:
- 37.1. refund any co-payments made by E to date in respect of the provision of Enbrel;

37.2. provide funding for the use of Enbrel to E from the date of this award without the requirement of co-payment and without an annual limit.

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P R JAMMY

Member: Appeal Committee

31 January 2008

I agree with the above ruling.

DR Z NJONGWE

Member: Appeal Committee

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[1] I have had the benefit of reading the draft prepared by the Chairman of the Appeal Committee, Adv Jammy, and am constrained to disagree with the route by which he arrived at his finding. While I agree that the therapeutic algorithm prescribed for rheumatoid arthritis by the regulations to the Medical Schemes Act, 131 of 1998,

(“the MSA”) requires the scheme to review and consider other Disease Modifying Antirheumatic Drug (“DMARD”) therapies where the patient member does not respond adequately to treatment with Non-Steroidal Anti-Inflammatory Drugs (“NSAID”), this must always be understood (as Note 2(c) to the algorithm requires) subject to “*all other applicable regulations made in terms of the Medical Schemes Act, 131 of 1998*”. One such “applicable regulation” is regulation 8, as the Chairman correctly points out. That said, the Chairman is correct in his conclusion that the scheme in this case is in contravention of regulation 8 in requiring the member to contribute 20% towards a drug (Enbrel) that both parties agree is the appropriate drug for the treatment of a Prescribed Minimum Benefit (“PMB”) condition.

- [2] But his confining of the focus of the draft to the meaning of “treatment” in regulation 8(1), with respect, loses sight of the overarching purpose for which PMB provisions were introduced in the MSA, namely, to keep the cost of healthcare services in South Africa low and affordable to consumers thereof. I also do not agree with the formulation by the Chairman of the issue that needs to be determined here. The issue in my view is not whether or not the scheme is correct in imposing on the member a 20% co-payment for

a drug necessary for the treatment of a PMB condition. That is clearly proscribed by regulation 8(1). Rather, the issue is whether the scheme can lawfully be compelled to fund the full cost of the drug even where such full cost is in excess of the scheme's own tariff schedule.

- [3] The answer in my view, as is demonstrated by the brief discussion that follows as regards the Legislature's intention in introducing PMB provisions in the MSA and regulations thereto, must be no. But that does not mean the member must then fund the balance of the full cost of the drug priced in excess of the scheme's tariff schedule. What it does mean is that the scheme must use its bargaining power and economies of scale to negotiate a lower cost for the drug with pharmaceutical companies that produce it. Until then, it must pay for the full cost of the drug even if in excess of its tariff schedule. While this is the conclusion reached by the Chairman, my reason for getting there is not so much that the scheme has the liability to fund Enbrel in full (that is, in excess of its tariff schedule) as that it would be depriving the member of a PMB treatment if it did not do so, a result that is contrary to the provisions of regulation 15I(c).

- [4] The relevant parts of regulation 8, subject to which the rheumatoid arthritis algorithm must be understood, read thus:

“(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.**

- (2) Subject to section 29(1)(p) of the Act, the rules of a medical scheme may, in respect of any benefit option, provide that –
- (a) the diagnosis, treatment and care costs of a prescribed minimum benefit will only be **paid in full by the medical scheme** if those services are obtained from a designated service provider in respect of that condition;
  - (b) ...”

(Emphasis supplied)

- [5] The question that arises is what does “*pay in full*” or “*paid in full*” mean in the context of the MSA? The Registrar has previously warned against interpretation of regulation 8(1) as providing for a “blank cheque”. In a circular 32 of 2006 dated July 2006 and addressed to all medical schemes, administrators and other stakeholders, the Registrar sought to reflect the Council’s interpretation of the PMB provisions in the MSA and regulations. He wrote:

“It should be understood that provision for full payment of PMBs applicable to involuntary use of non-DSPs is about guaranteeing access to care, and is not about providing a “blank cheque” to providers.”

- [6] The purpose behind the introduction of PMB provisions in the MSA was clearly to make healthcare services affordable. To that end, medical aid members are expressly exempt from paying for any emergency medical conditions and for the diagnosis, treatment and care costs in respect of those conditions listed in the regulations out of their own pockets. Rheumatoid arthritis is one such condition. The medical aid scheme must pay for these from the members' premiums.
- [7] That this exemption is limited in respect of those PMB healthcare services obtained voluntarily from designated service providers with whom the medical aid scheme would have negotiated favourable rates on behalf of its members is a clear indication that the Legislature's intention is to encourage the keeping of healthcare service costs affordable (regulation 8(2)(a)). This intention also becomes demonstrably clear from the fact that an out-of-pocket contribution may be imposed on a member who voluntarily obtains

such services from a service provider with whom his medical aid scheme has not negotiated a favourable rate (regulation 8(2)(b)). Only where a member obtains PMB healthcare services from a non-designated service provider involuntarily would the exemption from out-of-pocket contribution remain in place (regulation 8(2)(b)). This could arise in a number of ways. One could be an emergency situation. Another could be where there is no designated service provider facility in the area in which the member happens to be at the time PMB healthcare services are required (see regulation 8(3)).

- [8] With this clear intention in mind, the Legislature could not at the same time have intended to nullify the policy framework so carefully crafted to keep healthcare costs down, by quirkily compelling schemes to pay in full for every PMB drug priced in excess of its tariff schedule. The Legislature is presumed to be consistent with itself (see *Principal Immigration Officer v Bhula* 1931 AD 323 at 345). It could never, in my view, have at once intended to keep healthcare service costs affordable by enabling medical schemes to determine their rates and tariff schedules (section 29(1)(q)) and then expect them to pay for drugs that are priced in excess of that tariff schedule.

- [9] This carefully crafted policy framework begins with the Constitution of the Republic of South Africa, 1996, Act 108 of 1996 (“the Constitution”). Section 27 of the Constitution not only provides for the right of access to healthcare (s 27(1)); it also obliges the State to take reasonable legislative measures to ensure the realisation of that right (s 27(2)). That legislative measure has come in the form of a number of Acts of Parliament, among which is the MSA.
- [10] Section 29(1)(q) of the MSA obliges medical aid schemes to make provision in their rules for the payment of any benefits “*according to a scale, a tariff or recommended guide*”. Discovery Health’s scale, tariff or recommended guide is contained in table B of the Classic Comprehensive Plan to which the member subscribes. However, to the extent that the rule requires co-payment for a drug necessary for the treatment of a PMB condition, it cannot be sustained. The R100 000 annual limit on speciality drugs (such as Enbrel) for which the scheme’s funding protocol provides cannot be faulted. The difference between that limit and the full cost of the drug, however, cannot be for the member’s account.
- [11] But even assuming that the meaning of “pay in full” in regulation 8 clearly and unambiguously connotes full payment without limit based

on the scheme's tariff schedule, the absurdity to which such a literal interpretation would give rise is such that the only reasonable conclusion can only be that the Legislature could not reasonably have intended it. As Schutz JA pointed out in a unanimous judgment of the Supreme Court of Appeal in *Poswa v Member of the Executive Council for Economic Affairs, Environment and Tourism, Eastern Cape* 2001 (3) SA 582 (SCA) at paragraph [10], "*the literal meaning of an Act (in the sense of strict literalism) is not always the true one*".

- [12] Where that literal meaning would result in "*absurdity so glaring that it could never have been intended by the Legislature*" (per Innes CJ in *Venter v R* 1907 TS 910 at 914), or in "*absurdity, inconsistency, hardship or anomaly which from a consideration of the enactment as a whole a court of law is satisfied the Legislature could not have intended*" (per Stratford JA in *Bhyat v Commissioner for Immigration* 1932 AD 125 at 129), then a court is justified in departing from the clear and unambiguous meaning of the section (see also *Hanekom v Builders Market Klerksdorp (Pty) Ltd and Others* 2007 (3) SA 95 (SCA) at paragraph [7]). Thus, to the extent that regulation 8(1) is open to an interpretation that the scheme is liable to funding Enbrel in excess of its own funding limit as prescribed by its protocol, then the only reasonable conclusion must be that the Legislature could

not have intended it since that is clearly in conflict with the Legislature's intention of keeping healthcare service costs affordable.

[13] But that conclusion still begs the question of who pays for the balance of the cost of Enbrel in excess of the scheme's funding limit. The answer must clearly be the scheme because if the scheme does not pay and the member has no means to pay, the member will be deprived of a PMB treatment in contravention of regulation 15I(c). What remains is for the scheme to negotiate a lower price for the drug with pharmaceutical companies which it can then fund in full within its tariff schedule. Alternatively, it is for government to negotiate lower prices for certain drugs at the World Trade Organisation or produce generics where permissible.

[14] In the result, I would concur in the ruling not because the scheme is liable to funding Enbrel even in excess of its funding protocol limit but because its not doing so would result in the member being deprived of a PMB treatment. That would be in contravention of regulation 15I(c). There might conceivably arise a different set of facts on which a different conclusion might ensue.

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V NGALWANA  
Member: Appeal Committee  
31 January 2008

I agree with the above ruling.

Z LALLIE  
Member: Appeal Committee

THE APPEAL IS ACCORDINGLY UPHELD