

**THE COUNCIL FOR MEDICAL SCHEMES
APPEAL COMMITTEE**

In the Appeal between:

S H A

Appellant

and

FEDHEALTH MEDICAL SCHEME

Respondent

APPEAL RULING

1. The dispute between the parties concerns the refusal by the Respondent to fund six cycles of maintenance therapy with MabThera for the Appellant's condition of Mantle Cell Lymphoma ("MCL").

2. The Appellant submits that MabThera has now been accepted and is being administered by various oncologists in Europe and in the USA as a maintenance therapy for MCL, and relies heavily on the fact that the South African Oncology Consortium ("SAOC") has recently amended its Oncology Treatment Guidelines for Prescribed Minimum Benefits. Prior to the

amendment SAOC did not recognise MabThera as an appropriate maintenance treatment but have, since the amendment, recognised that such treatment is, indeed, appropriate.

3. The Respondent's submissions may be summarised as follows:
 - 3.1. whilst SAOC has recognised that MabThera is now an appropriate treatment, it has not elevated it to a recommended treatment *per se*, nor has it said that it is the only appropriate treatment;
 - 3.2. the SAOC approval of MabThera is not supported by first-level evidence-based medicine;
 - 3.3. whilst the SAOC has considered the clinical efficacy of MabThera, it is not necessary given full consideration either to the cost-effectiveness or affordability of the treatment;
 - 3.4. there are a range of conditions and types of non-Hodgkins Lymphoma, as well as a range of stages

that the disease reaches in particular patients. One cannot generalise and say that a therapy is appropriate for MCL as a rule. One has to consider the particular position of someone who, as in the case of the complainant, is in remission; and

- 3.5. the protocols that the Respondent has in place for the treatment of lymphoma are acceptable and adequate and comply with the requirements of the Medical Schemes Act and Regulations.
4. The debate before the Appeal Committee centered on whether the clinical efficacy of MabThera as a maintenance therapy for MCL had been adequately established. What was clear to the Committee was that reasonably persuasive arguments could be made for and against this proposal.
5. However, in the Appeal Committee's view, this is not the question upon which the answer to this appeal depends.
6. There is no obligation on a medical scheme to provide every and any particular treatment or therapy requested by its members.

7. Lymphoma is a Prescribed Minimum Benefit ("PMB") condition as defined in annexure "A" to the regulations promulgated under the Medical Schemes Act.
8. The effect of regulation 8 is that the 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.
9. The 'treatment' referred to in regulation 8 is the treatment specified in annexure "A". In the case of Lymphoma, that treatment is described as *"medical management which includes chemo therapy, radiation therapy, bone marrow transplantation"*.
10. the term 'medical management' must be interpreted with reference to the explanatory notes and definitions to annexure "A". Note 2 provides as follows:

"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 hospitals, 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. The following interventions shall however be excluded from the general medical/surgical management categories unless otherwise specified:

- i) tumor chemotherapy;*
- ii) tumor radiotherapy;*
- iii) bone marrow transplantation/rescue;*
- iv) mechanical ventilation;*
- v) hyperbaric oxygen therapy;*
- vi) organ transplantation;*
- vii) treatments, drugs or devices not yet registered by the relevant authority in the Republic of South Africa.*

11. With regard to chemotherapy and bone marrow transplantation note 4 to annexure "A" provides as follows – *"tumor chemotherapy with or without bone marrow transplantation and other indications for bone marrow transplantation – these are included in the prescribed minimum benefit package only where annexure "A" explicitly mentions such interventions. Management may include a first full course of chemotherapy, (including, if indicated, induction, consolidation and myeloablative components). Where specified in terms of annexure "A", this may be followed by bone marrow transplantation / rescue, according to tumor type and prevailing practice. The following conditions would also apply to bone marrow transplantation components of the prescribed minimum benefits:*

- i) The patient should be under 60 years of age;*
- ii) Allogeneic bone marrow transplantation should only be considered where there is an HLA matched family donor;*
- iii) The patient should not have relapsed after a previous full course of chemotherapy for (i and ii shall also apply to bone marrow transplantation for non-malignant diseases)."*

12. What is apparent from the foregoing is that the Respondent is under no obligation, in terms of the Act or the Regulations, and as part of its treatment of MCL as a prescribed minimum benefit to provide MabThera as part of its treatment protocol.
13. Regulation 8(4) expressly authorises a scheme to employ appropriate interventions aimed at improving the efficiency and effectiveness of health care provision, including such techniques as requirements for pre-authorisation, the application of treatment protocols and the use of formularies.
14. That a scheme may adopt protocols or formularies is recognised, too, in regulations 15H and 15I, both of which provide that the protocol, formulary or restricted list of drugs must be developed on the basis of evidenced-based medicine, taking into account considerations of cost-effectiveness and affordability. Both of these regulations require that provision must be made for exceptions where a protocol in the former case or a formulary drug in the latter case has been ineffective or causes or would cause harm to the beneficiary. In such cases the exception or substitution must be available without penalty to the beneficiary.

15. It is in light of these provisions that the Appeal Committee is of the view that the debate before it has been misdirected. The relevant question is not whether MabThera is acceptable according to medicine-based evidence and considerations of cost effectiveness. The correct question is whether the treatment protocol adopted by the Respondent meets those criteria. If it does, then it falls within the requirements of regulations of 15H and 15I as well as the requirements of regulation 8. In those circumstances the Respondent is entitled to impose its treatment protocol on its members, regardless of the fact that there may be other appropriate treatments available.
16. No evidence was placed before the Appeal Committee to demonstrate that the treatment protocol used by the scheme falls foul of the requirements of the regulations. Likewise it was not contended that either that protocol, or the formulary drugs used by the Respondent would be ineffective or had caused harm or would cause harm in the Appellant's case.
17. It may well be that MabThera is an acceptable and clinically appropriate alternative to the treatment protocol employed by the Respondent. Even if that were established (and as has been

seen, this is subject to considerable debate) the result would not be to compel the Respondent to provide MabThera to the Appellant.

18. In the circumstances the Appellant has not established or demonstrated a right to the treatment which she seeks. The consequence is that the appeal is dismissed.

DATED at JOHANNESBURG on the day of JANUARY 2008

P R JAMMY

For: Appeal Committee