Accessing appropriate treatment for Prescribed Minimum Benefits

A doctor's guide to securing treatment despite scheme rules

There is a lot of confusion and misinformation concerning medical scheme funding for specialised treatments like biologics and biosimilars. Most people believe these treatments are only funded on the highest plan types. Some know that scheme rules can be challenged but are unsure where to start. Few people can confidently describe the circumstances in which patient rights trump scheme rules and how to enforce them.

My name is Catherine McCormack. I'm a mom to a child with a chronic autoimmune condition and via Arthritis Kids South Africa and The Autoimmune Alliance of South Africa, I have helped medical aid members secure funding for specialised treatments like biologics where funding has been refused.

How did I do it?

It is helpful that I had the time. I'm tenacious by nature, and this helped too. My self-proclaimed title of 'patient advocate' gave me a sense of purpose and, in turn, confidence: I am certainly braver as Catherine McCormack, Executive Director of The Autoimmune Alliance of South Africa than I am as Cath McCormack, stay-at-home mom.

But ultimately, my success is a testament to the unambiguity of the law and the reliability of the Council for Medical Schemes' Complaint Process.

Simply put, I won because it's the law + the law is enforceable via a reliable regulator.

I'm sharing my experience because I believe medical schemes have created unnecessary complexity through inaccurate and misleading communications and, in the process, have convinced us that their rules are absolute.

While it's true that schemes are permitted to limit funding in a myriad of ways, there are well-defined circumstances where patient rights supersede the rules.

I hope to enable you to recognise these circumstances so you can guide your patients towards self-advocating for the treatments they need.

Contact

info@autoimmunealliance.co.za at any point for assistance in this regard. We are here to help.

NOTE: *The principles I describe in this guide relate to any appropriate diagnosis, treatment* or care cost for any Prescribed Minimum Benefit Chronic Condition, but I focus on biologics (which includes biosimilars) as these are usually the most contentious.*

**Including Section 21 medicines where there is relevant, up-to-date, credible evidence in support of the treatment for a particular patient.*

The Medical Schemes Act 131 of 1998 and Regulations (1999) (MSA)

In supporting patients to fight for their rights, it is helpful to know a little about the MSA and the supporting regulations, specifically Regulation 8: Prescribed Minimum Benefits (PMBs) and Regulations 15H and 15I that deal with protocols and formularies, respectively. Please don't be put off by the legalese; none of this is especially challenging to understand.

Regulation 8 of the MSA says:
"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"

As you may know, PMBs include all medical emergencies, 271 medical conditions, 25 chronic diseases and HIV.

PMBs aim to enable continuous and appropriate care cost-effectively. This is a tall order, and the financial burden of funding all diagnosis, treatment and care costs for this complete list is not insignificant.

The MSA deals with this by allowing schemes to manage the costs of 'PMB care' through tools like formularies, protocols, and designated service providers and by requiring pre-authorisations, all of which aim to enable cost-effective appropriate and continuous care.

Managing 'PMB care' works for patients who respond to formulary drugs, have reasonable access to service providers, and whose allied healthcare needs fall within benefit limits – in other words, most patients.

But managed health care inevitably results in a group of patients for whom the MSA no longer applies, namely, those who don't respond to formulary treatments or can't use them, have no reasonable access to service providers, or whose allied and other healthcare needs fall beyond the benefit limits.

This is remedied in Chapter 5 of the Medical Scheme's Regulations: Provisions of Managed Health Care.

The rule of thumb is this:
Do scheme rules make it impossible for your patient to have their PMB diagnosis, treatment and care costs met? If so, relief is almost certainly to be found in the managed health care chapter of the Medical Scheme Regulations, specifically Regulations 15H and 15I, which say:

15H. Protocols
If managed health care entails the use of a protocol –

(a) such protocol must be developed on the basis of evidence-based medicine, taking into account considerations of cost-effectiveness and affordability;

(b) the medical scheme and the managed health care organisation must provide such protocol to health care providers, beneficiaries and members of the public, upon request; and

(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.

15I. Formularies
If managed health care entails the use of a formulary or restricted list of drugs –

(a) such formulary or restricted list must be developed on the basis of evidence-based medicine, taking into account considerations of cost effectiveness and affordability;

(b) the medical scheme and the managed health care organisation must provide such formulary or restricted list to health care providers, beneficiaries and members of the public, upon request; and

(c) 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.

The key concepts are "evidence-based medicine", "exceptions", "substitutions", and "appropriate", but in short, to secure a biologic despite scheme rules or to reverse a co-payment, the formulary or protocol must not contain any appropriate treatment options either because:

- these treatments were ineffective,
- the order in which the treatments should be used is contraindicated,
- the treatments caused an adverse reaction,
- the treatment or protocol caused or would cause harm to the patient.

Also, note that appropriate treatments can only be included or excluded by any party on the basis of evidence.

Determining 'appropriate'

The point of departure for determining 'appropriate' for PMB chronic conditions are the treatment algorithms from the Department of National Health.

The treatment algorithm is the minimum below which no scheme may fall; all schemes must fund all treatments mentioned in the algorithm, regardless of plan type. Schemes may fund additional treatments over and above those listed in the treatment algorithm, either as part of the formulary or from separate benefits, for example, Discovery Health's Specialised Medicine and Technology Benefit.

To access treatments not listed in the treatment algorithm AND not included in a plan type's formulary or special benefit, the patient must meet specific criteria, which I discuss in a later section.

All treatments applied for must be 'appropriate', which Elsabe Klinck of Elsabe Klinck and Associates says meet the following criteria:

1. Evidence-based: treatment supported by research and other reputable data sources, taking patient specifics into account. The research and/or guidelines must be up to date; the law talks about "current" and "best" evidence. Appropriate may even include off-label prescriptions or the prescription of treatment outside of outdated local guidelines but based on updated global guidelines.

2. Appropriateness also means that the healthcare professional has been trained and is experienced in treating the type of patients. The Health Professions Council of South Africa (HPCSA) determines the scope of a profession, and medical schemes cannot set limitations on any profession or speciality if the HPCSA allows such activity.

A special note on children

Children get a special mention in the **treatment algorithms.**

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.

The case for children is further strengthened by the **Children's Act** which contains strong provisions that bind all decision-makers: schemes, doctors, and parents. The Children's Institute published a **helpful guide** in 2013, and this excerpt speaks to the general principle of 'best interests of the child':

"The importance of considering the best interests of the child in all matters that affect the child is recognised in both the UNCRC and the African Charter on the Rights and Welfare of the Child. The Constitution notes that "a child's best interests are of paramount importance in every matter concerning the child. ***This includes matters affecting the health and well-being of the child. The Children's Act stipulates further that the best interest standard must be applied in all matters concerning the protection, care and well-being of the child. Thus in all decisions, actions and proceedings regarding the health and well-being of children the best interest standard must be applied."***

Section 11 of the Children's Act includes the following:

11. Children with disability or chronic illness

(2) In any matter concerning a child with chronic illness due consideration must be given to—

(a) providing the child with parental care, family care or special care as and when appropriate;

(b) providing the child with conditions that ensure dignity, promote self-reliance and facilitate active participation in the community; and

(c) providing the child with the necessary support services.

Securing access to treatment

Phase 1: Make the case

A case for a non-formulary treatment or a change to accepted protocol is made or lost on the medical merits of the case, which you must establish on your patient's behalf.

Your application to the medical scheme must include a motivation that describes why the prescribed treatment is most appropriate and, importantly, why other options are inappropriate. Support your argument with evidence and share the information with your patient.

It is also helpful to reference the legal regulations triggered by your patient's case. Here are some sample sentences to get you on your way:

1) When you need to treat outside of the formulary:

This patient's case triggers Regulation 15I(c) of the Regulations to the Medical Schemes Act 131 of 1998:

- *available formulary drugs are ineffective (include relevant treatment history and describe evidence of persistent disease) OR*
- *available formulary drugs have caused an adverse reaction (report the reaction to SAHPRA and describe in your motivation)*

2) When the protocol cannot be followed because an early use of a biologic is supported by evidence or the patient has an underlying condition that precludes the protocol, for example.

This patient's case triggers Regulation 15H(c) of the Regulations to Medical Schemes Act 131 of 1998:

- *the protocol has harmed/ will harm the patient (add reason/s)*
- *(reason/s) renders the protocol ineffective for this patient.*

In my first case, I used Reg 15I (which deals with formularies) when I should have used Reg 15H (which deals with protocols). The CMS Clinical Review Committee (CRC) overlooked this technicality and ruled in favour of the patient because the medical merits of the case were valid. You don't need to be a lawyer to submit a complaint, but if CMS CRC can't find enough medical support for the claim, your case will be dismissed- as it should be! The intention is to enable appropriate and necessary access, not take advantage.

Phase 2: Apply!

This may seem obvious, but I know some of you have given up applying for biologics where you believe there is no hope of funding.

Before your patient can register a claim with the CMS, there must be evidence of 1) the scheme having denied funding and 2) attempts to resolve the dispute with the scheme directly.

Phase 3: Complain!

If the scheme continues to decline, it is time to submit a complaint to the CMS.

I don't think it is practical for doctors to do this on behalf of patients, but it is worth noting that some patients will be too overwhelmed, intimidated or otherwise unable to follow this process through. In these cases, you will either need to do it for them or refer them to someone who can.

I continue to process complaints on behalf of children with JIA at no charge, so feel free to refer these families to me. Refer other patients to the Autoimmune Alliance of South Africa or relevant patient advocacy group.

The CMS process works but takes time: manage expectations! Allowance is made for clinically urgent cases, but the usual turnaround is:

- 30 days for the scheme to respond from the time CMS acknowledges the complaint,
- 90 days for CMS to review the case if the scheme continues to deny funding and issue a ruling
- 90 more days, during which time the parties can appeal the ruling

Most of my cases were resolved within 60 days of submitting the complaint, and some within two weeks, but the entire process can take a full seven months.

You might be wondering why the schemes persist in denying funding if it is such a blatant contravention of the applicable laws? It's an excellent question to which I don't have an adequate response. But I'm working on it! My objective is for all applications to be assessed by scheme rules AND the law, rather than only the former. Patient rights should not only apply to those lucky enough to know about them and with the resources or support to act.

NOTE: *I have never seen a scheme communication that included a reference to treatment access outside of scheme rules. Don't be deterred! Ask: do the scheme rules preclude my patient from having their PMB rights met? If yes, look to the MSA and the associated regulations for an answer and the Council of Medical Schemes for support.*

Terms

MSA: Medical Schemes Act 131 of 1998, to which regulations were issued in 1999
CMS: Council for Medical Schemes
CRC: Clinical Review Committee (of the CMS)
PMB: Prescribed Minimum Benefits

To do!

* Develop a better understanding of the Managed Health Care Regulations so you can recognise when to use them.
* Enable your patient to act on a rejection by explaining the basis for their right to treatment and sharing your motivation and application.

The Autoimmune Alliance of South Africa is a non-profit organsation manned by volunteers. Please consider a donation if this has improved your ability to support your patients or reduced your admin load.

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