The Council for Medical Schemes

Managed Care Protocol Guideline

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1. INTRODUCTION

Any organisation providing managed health care services as defined in Regulation 15, is required to be accredited as a Managed Care Organisation (MCO). Managed care clinical protocols (and where relevant formularies as well) are employed in the delivery of the managed care services to client medical schemes. Such protocols (and formularies, where applicable) must be in compliance with the Medical Schemes Act (Act 131 of 1998) ("the Act"), the Regulations promulgated in terms of the Act, and the applicable managed care accreditation standards published from time to time.

This guideline is intended to assist MCOs in developing and implementing protocols (and formularies, where applicable) in compliance with the requirements and in the best interest of the medical scheme beneficiaries affected thereby.

2. RELEVANT LEGISLATIVE PROVISIONS / REQUIREMENTS

2.1 Regulation 15 – Definitions

- ***"evidence-based medicine"*** means the conscientious, explicit and judicious use of current best evidence in making decisions about the care of beneficiaries whereby individual clinical experience is integrated with the best available external clinical evidence from systematic research"
- ***"managed health care"*** means 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 rules-based and clinical management-based programmes"
- ***"protocol"*** means a set of guidelines in 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"
- ***"rules-based and clinical management-based programmes"*** means a set of formal techniques designed to monitor the use of, and evaluate the clinical necessity, appropriateness, efficacy, and efficiency of, health care services, procedures or settings, on the basis of which appropriate managed health care interventions are made.

2.2 Other

- ***Regulation 15D – Standards for managed health care –*** Encompasses the written protocol requirements;
- ***Regulation 15G – Limitation on disease coverage –*** Details the way in which such limitations must be developed and communicated;
- ***Regulation 15H – Protocols –*** General requirements regarding the development and implementation of protocols; and
- ***Regulation 15I – Formularies -*** General requirements regarding the development and implementation of formularies.

3. MANAGED CARE PROTOCOL TEMPLATE GUIDELINE

The suggested template below is by no means exhaustive but includes the required information to satisfy the legislative and managed care accreditation standards requirements with regards to the development and implementation of managed protocols (and formularies, where applicable).

Where relevant, the specific managed care standard relating to a component is referred to; else the components refer to the protocol / formulary related standards in general (refer to section 4 of the published *managed care accreditation standards (Version 5).

* The managed care accreditation standards were developed to incorporate the legislative requirements as well as general best practice from a practical implementation point of view.

Component	Explanatory comments	Managed care accreditation standard (Version 5)	
		Ref(s)	Description
1 Objective / Purpose	Describe what the MCO aims to achieve with the development and implementation of the protocol	N/A	
2 Schemes and benefit options to which the protocol (and formulary, where	Self-explanatory	N/A	

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		Ref(s)	Description
applicable) is applied.			
3 Beneficiary entitlements and limits	Relevant entitlements / limits approved for funding in terms of the protocol (and formulary, where applicable); and aligned to the Act and registered scheme rules.	4.1.4	The managed care protocols and formularies contain details of any limitations, exclusions, designated or preferred provider networks, etc. in line with the registered scheme rules of each scheme.
4 Detailed clinical entry / eligibility criteria including applicable ICD 10 codes	• Detailed description of the entry / eligibility criteria. • Relevant ICD10 codes approved for funding in terms of the protocol; and aligned to the Act and registered scheme rules. • How does the beneficiary / health care provider apply to access the benefit, including the communication for approved, pended, and declined applications.	4.2 (4.2.1 & 4.2.2)	Appropriate clinical coding rules are applied to the managed care protocols and formularies
		4.1.5	The managed care protocols and formularies incorporate procedures to evaluate clinical necessity (clinical entry criteria), appropriateness, efficiency and affordability of services provided, to intervene where necessary and to inform beneficiaries, providers of care acting on their behalf, and medical schemes of the outcomes of such procedures.
5 Basket of care / care plan / treatment plan / authorisation	• Indicate whether the protocol / formulary entitlements are funded from the chronic medication, PMB, benefit option benefit limit, savings, etc. • Indicate all relevant CPT, Nappi and other relevant tariff codes.	3.1.3	The managed health care programmes include any limitations on rights or entitlements of beneficiaries including, but not limited to

Component	Explanatory comments	Managed care accreditation standard (Version 5)	
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	• Detail any exclusions, e.g. related to prosthesis, procedures, etc. • Clearly indicate the specific health care provider types, health care facilities, settings, etc. covered under the protocols.		restrictions on coverage of disease states, protocol requirements and formulary inclusions or exclusions. (Regulation 15D(e)(iii))
		4.1.4	The managed care protocols and formularies contain details of any limitations, exclusions, designated or preferred provider networks, etc. in line with the registered scheme rules of each scheme.
		4.1.6	The managed care protocols and formularies are made available to beneficiaries on registration and at least annually (where applicable, e.g. annual disease management treatment plan) and on request.
6 Formulary inclusions and exclusions.	• The formulary must be readily available and easily accessible by both beneficiaries and health care providers. • The process to follow in case of an exception and co-payment should be clearly communicated to all stakeholders.	4.1.4	The managed care protocols and formularies contain details of any limitations, exclusions, designated or preferred provider networks, etc. in line with the registered scheme rules of each scheme.
7 Exception / appeal process	• Clearly detail the process to follow should the member need to access clinically appropriate additional / alternative services.	4.1.9	The organisation is able to clearly illustrate that managed care protocols and formularies

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	• Clearly detail the process to follow should a member / provider wish to appeal any decision relating to a protocol / exclusion / etc.		allow for an appropriate exception / appeal process by beneficiaries or providers where the recommended treatment in respect of the protocol / formulary is or has been ineffective, or causes or would cause harm to a beneficiary, without penalty to such beneficiary.
8 Co-payments applicable	• All relevant (and appropriate) co-payments should be clearly indicated. • Clearly indicate the process to follow should PMB diagnosis be confirmed after investigative tests have been done, to ensure any relating co-payments charged are reprocessed and paid correctly from risk benefits.	4.1.11	Co-payments are in line with the registered scheme rules, managed care protocols and formularies and are clearly communicated to beneficiaries when services are requested / obtained. (Beneficiaries should not be subjected to any co-payments should the beneficiary request / obtain any healthcare service in line with the documented managed care protocols and formularies.).
9 Evidence-based medicine references	Current / most recent literature Evidence-Based Medicine (EBM) ought to combine individual clinical expertise with the best available evidence from clinical research and systematic reviews including the opinions of respected authorities, based on clinical experience, descriptive studies, or reports of expert committees, in order to make decisions about the care of individual patients. Please refer to the following links for more information on the hierarchy of the levels of evidence: • https://canberra.libguides.com/c.php?g=599346&p=4149721	3.2.1	The managed health care policies and procedures include details of the clinical review criteria used (based on evidence-based medicine) in consideration of cost effectiveness and affordability with regard to funding

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	• https://www.ncbi.nlm.nih.gov/pmc/articles/PMC3124652/		decisions. (Regulation 15D(b)).
10 Last protocol update / review date	• Version control should be exercised by the MCO and it should be clearly indicated when the protocol was last updated / reviewed. • Protocols should be reviewed at least every two years, and formularies at least annually.	3.2.2	The clinical review criteria used (based on evidence-based medicine) in consideration of cost effectiveness and affordability are evaluated at least every two years to ensure relevance of funding decisions. (Regulation 15D(b))
11 Name(s) and qualification(s) of the individual / panel who reviewed the protocol.	Self-explanatory	4.1.2	The organisation is able to clearly illustrate that managed care protocols are reviewed by an appropriate clinical review committee / expert for continued appropriateness and cost-effectiveness at least every two years.
		4.1.3	The organisation is able to clearly illustrate that managed care formularies are reviewed by an appropriate clinical review committee / expert for continued appropriateness and cost-effectiveness at least annually