South African Rheumatism and Arthritis Association

Policy document and Standard operating procedure for the SARAA Biologics Advisory Peer Review Panel

(hereafter referred to as the "Panel")

1. Aim of the panel

1.1. This Panel was constituted to assess the eligibility of patients with rheumatic diseases who commence biologic therapies. It also assesses the eligibility of patients to continue with biologic therapies. It then makes non-binding recommendations on the findings of such eligibility assessments.

1.2. This is done to assist in the reimbursement process to ensure, within the limitations of such a review process as outlined below, the appropriate and evidence-based use of such products, as is required by medical schemes legislation.

2. Biologic Advisory Peer Review Panel

2.1. The panel is overseen by a biologics panel manager who is appointed by the SARAA executive committee, in terms of the powers awarded to it under the SARAA Constitution.

2.2. The panel consists of a minimum of eight (8) rheumatologists one of whom is the biologics panel manager.

2.3. The panel members must be practicing rheumatologists and active members of SARAA.

2.4. The process of appointment of a panel member will be based on a member volunteering to be on the panel. Should sufficient volunteers not be found, a process of nomination will be followed and the SARAA Executive Committee shall, based on such nominations, appoint the remaining number of members.

2.5. Duration of appointment of a panel member will be for a minimum of two years with a possibility of reappointment or re-volunteering.

2.6. Resignations may be voluntary at any time during the two year period provided that not more than two panel members resign at the same time.

3. Process

3.1. General principles

3.1.1. In exercising the powers in terms of this policy, the Panel shall adhere to the principles of administrative justice, including but not limited to -

3.1.1.1. Ensuring that there are no conflicts of interests in relation to any particular patient, practitioner and/or funder. The panel shall refrain from assessing their own request for his/her own patient to prevent conflicts of interest;

3.1.1.2. Ensuring that all deliberations are documented, and all decisions are justifiable in view of the decision taken;

3.1.1.3. Ensuring that no extraneous considerations are taken into account when making a decisions;

3.1.1.4. Ensuring that decisions are based on the definition of what would constitute evidence-based medicine as is defined by medical schemes legislation, as manifested in the SARAA clinical criteria as published on the SARAA website; and

3.1.1.5. Ensuring that decisions are taken expeditiously.

3.1.2. The biologics panel manager shall ensure that a rheumatologist does not evaluate his/her own submissions.

3.1.3. All patient and clinician data shall be presented to the panel in an anonymised format, brought about by the biologics panel manager.

3.1.4. The panel manager shall ensure that all information remains confidential and shall ensure that no remarks or comments are made which could reveal the identity of any party or entity involved. The panel manager shall also ensure that the name of the particular scheme and scheme option are removed from all documentation

3.1.5. The outcome of the panel decision will be communicated to the treating clinician and the medical funder where necessary, through the offices of the biologics panel manager.

3.1.6. The decisions of the panel shall not be binding on any party, but will carry persuasive weight on what constitutes a peer review agreement on what would constitute appropriate therapy for a patient, given the information before the panel.

3.2. Process for new patients

3.2.1. When a new patient is thought to be eligible for biological therapy for a rheumatic disease, the clinician will complete the appropriate submission form (attached as form "A") and submit this to the biologics panel manager.

3.2.2. The patient and clinician details will be presented in an anonymised way to the panel members.

3.2.3. The panel will review the proposed biologic therapy. This review will be based on the clinical information provided by the treating clinician and not on a clinical examination of the patient, using the SARAA biologic eligibility criteria, as published from time to time in terms of the SARAA Constitution.

3.2.4. The decision for biological therapy will either be recommended or not recommended.

3.2.5. All panellists will receive the information to be assessed.

3.2.6. The decision of the panel will be based on at least two (2) panel members either recommending or not recommending the proposed initiation of biologic therapy.

3.2.7. If the panel recommends a biologic therapy in a patient who does not fulfil the criteria, then this must be accompanied by an adequate explanation of the decision taken, which must be provided to the treating clinician.

3.3. Process for ongoing therapy

3.3.1. In patients who require ongoing use of the biologics therapy, the clinician will need to complete the follow-up submission form (attached as form "B") and submit this to the biologics panel manager.

3.3.2. The patient and clinician details will be presented in an anonymised way to the panel members.

3.3.3. This review process will be based on the clinical information provided by the treating clinician and not on a clinical examination of the patient, using the SARAA response criteria for biologic therapy, as published from time to time in terms of the SARAA Constitution.

3.3.4. The decision for continuing biological therapy will either be recommended or not recommended.

3.3.5. The decision of the panel will be based on two (2) panel members either recommending or not recommending a request to continue the therapy.

3.3.6. If the panel recommends the ongoing use of a biologic therapy in a patient who does not fulfil the criteria, then this must be accompanied by an adequate explanation for the decision taken.

4. Appeal process

It is acknowledged that the medical scheme, the patient or the medical practitioner may feel aggrieved by the decision of the panel. In such cases, the parties are free to utilise the SARAA internal appeals processes whereby the submission is then reviewed by all eight (8) panel members. In case of a hung vote, the casting vote will be with the panel manager.

5. Rights of doctors, patients, etc.

Nothing in this process shall be construed as detracting from rights of doctors, patients or medical schemes to, at any stage approach the Council for Medical Schemes, the scheme or another party directly, or to act in any manner to protect or advance their rights or interests.

6. Lack of accessibility of the public to a rheumatologist

Whatever the reason may be for lack of accessibility, the panel will only review applications from registered rheumatologists with the HPCSA. This is not to say that only rheumatologists in South Africa can prescribe biologics, but rather that the panel is only mandated to review applications from registered rheumatologists. Should a non-rheumatologist wish to prescribe a biologic, regardless of the indication then the panel should no way hinder that process. The decision for funding of a biologic is then between the patient / funder and prescribing physician.

7. Liability

7.1. The panel and none of its members shall not be held liable jointly or severably for any recommendation is makes in terms of this policy.

7.2. The panel can only act on the information supplied to it, and cannot be held liable for any deductions it makes on the information before it.

7.3. The panel only makes recommendations, based on its understanding of evidence-based medicine at that particular point in time. The final decision on the treatment a patient receives lies with the doctor and his or her patient. The final funding decision lies with the specific medical scheme.

FORM "A1,A2,A3" NEW PATIENTS ON BIOLOGICS

FORM "B1,2,3" SUBMISSION FOR CONTINUED TREATMENT WITH BIOLOGICS

FORM "C": PRO FORMA RESPONSE BY PANEL TO PRACTITIONER/MEDICAL SCHEME

"The SARAA Biologics Peer Review Panel has considered the submission relating to the appropriateness of treatment of the patient with a biologic. This assessment is based solely on the information provided by the treating clinician and not on a clinical examination of the patient. The decision of the panel is therefore limited to the information before it. It should not be construed as supersession of active care of the patient. The decision is also not binding on any party and constitutes an advisory opinion of the process of peer review of recommended treatment, within the SARAA Guidelines for Biological Therapy, as amended from time to time. The panel shall not be responsible for any incorrect, incomplete or uncontextualised clinical and other information that is provided. The panel shall also not be responsible for any treatment outcome, or lack thereof, should the clinician and/or medical scheme choose to follow, or not to follow, the decision of the panel.

The decision is as follows:_____

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and is based on the application of the following SARAA criteria (list specific criteria with reference to specific version, dates and paragraphs, and/or scientific principles, where and as applicable): ___

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