SARAA
South African Rheumatism & Arthritis Association
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SARAA POSITION STATEMENT ON BIOLOGICS USE IN SOUTH AFRICA

Introduction

Biologic disease modifying antirheumatic drugs (bDMARDS), biosimilar DMARDS (bsDMARDS) and targeted synthetic DMARDS (tsDMARDS) are advanced or specialised treatments that have greatly improved the outcomes of patients with systemic rheumatic diseases (SRDs), including inflammatory arthritis (rheumatoid arthritis (RA), spondyloarthritis (SpA) including psoriatic arthritis (PSA) and juvenile idiopathic arthritis (JIA)) and connective tissue diseases (systemic lupus erythematosus (SLE), inflammatory myositis, systemic sclerosis).

Suboptimal or delayed treatment can result in significant morbidity and mortality, as a result of uncontrolled inflammation, disease or drug (most notably corticosteroid) related damage, as well as comorbidities such as infection and cardiovascular events. In SLE, major organ involvement, including kidney, CNS or cardiac, often does not respond to conventional treatments, and urgent use of specialised therapies may be required to avoid devastating consequences.

In RA ongoing disease activity can lead to damage, deformity and considerable disability, which impacts on a patient's overall quality of life, including physical, mental, psychological, social and work-related function. This can occur as early as 6 months into the disease course, despite the use of conventional DMARDs. For this reason, both national and international guidelines aim for achievement of remission or at least a low disease activity state by 6 months.

SARAA recommendations on the use of biologics and other specialised therapies serve as a guide for prescribing, monitoring safety and assessing treatment response. They are specific to South Africa, taking into account factors such as tuberculosis (TB), an important complication in this country. They are updated periodically.

In addition to the guidelines, SARAA provides oversight of patients with SRDs on specialised therapies through the SARAA biologics registry and approval system; an anonymised database and portal for peer review.

The SARAA biologics working group highlights the following fundamental positions on the use of bDMARDs, bsDMARDs and tsDMARDs for SRDs in South Africa. These are discussed in greater detail in our disease specific and general biologics use recommendations.

• Specialised treatments including bDMARDs, bsDMARDs and tsDMARDs should be **prescribed by a rheumatologist** with experience in the diagnosis, treatment and monitoring of patients with SRDs.

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- Patients that are to initiate these therapies **must complete a prescreening workup, which includes TB screening,** and should **receive a SARAA biologics panel approval.**
- There are many different mechanisms of action of these advanced treatments and as such they are **not all interchangeable.**
- Choice of bDMARD, bsDMARDS or tsDMARDs is **determined by patient, clinical** and **disease-related factors**, as well as **potential risks** which **differs between individual patients.**
- In South Africa, infectious complications, particularly **TB must be considered when choosing an appropriate biologic.** For example, in high-risk individuals TNF inhibitor (especially TNF monoclonal antibodies) may not be the most favourable treatment choice.
- Patients on these treatments must be **monitored at regular intervals for clinical response,** using validated quantitative response measures, and for **adverse events.** Response to treatment and the development of adverse effects varies from patient to patient, as well as in an individual.
- Patients with a **good clinical response** should be **maintained on their prescribed treatment** with the aim of achieving sustained remission.
- Patients with suboptimal clinical response or adverse events **may require to be switched to another treatment. This may occur multiple times in any individual and is often unpredictable.**
- These therapies are not interchangeable, as such rheumatologist prescribed treatment **cannot be substituted by a pharmacy or medical funder.**

The SARAA biologics working group highlights these fundamental positions on the role of SARAA, government, the medical funders and pharmaceutical companies in the consideration of health care costs and health economics in South Africa,.

• SARAA is committed to maintaining the **highest standard of care** in patients with SRDs, acknowledging the limitations in health resources, economic instability and financial situation of individual patients.

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- SARAA advocates using the **most appropriate and cost-effective treatment** in each patient, through a shared informed decision between the patient and treating rheumatologist.
- SARAA has **welcomed the registration of bsDMARDs** and provided clear position on the place and use of these drugs, to improve access for patients, if and when the relevant originator product is more costly. (See SARAA position statement on bsDMARDs – www.saraa.co.za)
- We acknowledge that pharmaceutical companies have lowered prices on certain therapies to improve access, and encourage them to **continue to review pricing to increase affordability and access** to those in need.
- We encourage and emphasize **the importance of bringing new innovative treatments** into the country. This is to ensure our patients have fair access to current, effective and appropriate treatments that meet international standards.
- SARAA urges government, the national department of health essential drugs programme, along with national and provincial pharmacotherapeutic committees (PTCs) to **broaden access to bDMARDs, bsDMARDs and tsDMARDs for ALL patients with SRDs.** This should include access to a wider range of specialised targeted therapies to treat the various SRDs.
- SARAA appeals to the council of medical schemes to **consider a unified diagnosis of inflammatory arthritis**, so as not to exclude equally disabling arthritis such as SpA, including axial SpA, PsA and JIA from the prescribed minimum benefit (PMB) conditions list. This will allow for a better understanding of the burden of rheumatic diseases in the country. It will also ensure that these **conditions are funded uniformly.**
- SARAA **supports reasonable pricing** of drugs, but is **opposed to therapeutic reference pricing**, due to its negative impact on patient health, loss of clinician decision-making, attrition of incentive to access new treatments and impediment to fair pricing. We understand the growing burden of healthcare costs and its impact on state, private and funder affordability. We acknowledge the role of reference pricing in

reducing cost. However, **cost-cutting measures targeting drug expenditure alone is not effective or sustainable in containing overall healthcare costs**. In SRDs major cost drivers include recurrent hospitalisations from disease and its complications, joint replacement surgery, fracture services, work absenteeism and loss of employment with funding support, disability and its impact on the economy.

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- We are **opposed to the incurrence of co-payments** for patients with SRDs established and controlled on treatments that were once funded, due to regular lowering of reference prices determined without insight into the individual drug biology. Similarly, patients not responding to more cost-effective drugs that need to be switched, should not be penalized co-payments.
- SARAA **does not take responsibility for the prescription of inappropriate treatments** based on cost constraints, nor pressure from funders; and should follow local SARAA management recommendations or international guidelines, which are evidence based.
- SARAA **prioritises quality patient care to ensure a meaningful quality of life**. This includes access to potentially life-altering treatments. The right to healthcare is part of our constitution, and should be accessible to all individuals, regardless of whether they are accessing government or private facilities.
- **Collaboration, consideration and transparency between SARAA, patient organisations, academic institutions, national department of health, medical funders and pharmaceutical companies will improve the delivery of best care to our patients. This should be maintained through regular engagement, clear communication lines and accountability from all parties.**

The SARAA biologics working group and SARAA executive, on behalf of its members.

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