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SOUTH AFRICAN ONCOLOGY CONSORTIUM

Guidelines for Pharmaceutical Company Applications for SAOC Treatment Guideline Inclusions

Pharmaceutical companies may submit applications for inclusion of therapies into the existing SAOC Treatment Guidelines.

Process

Submissions are to be addressed to the **Chairman, SAOC URC Committee**.

Submissions will be reviewed by the URC Committee taking into account the SAOC URC Guidelines and the objectives of the SAOC.

These objectives may differ between the different tiers on the tiered protocols

The applicant will be informed of the decision in writing.

E-mail submissions: maryke@saoc.org.za

Fax submissions: 086 607 5166 for attention Dr M Schickerling

Postal submissions: PO Box 10053, Centurion, 0046 for attention Dr M Schickerling.

Format

The application must be in writing.

Details included in the application should include but are not limited to:

1. The indication applied for should be specified in detail e.g. Disease – metastatic breast cancer indications

    a) *First-line treatment of metastatic breast cancer in hormone-refractory patients with prior exposure to anthracyclines in the adjuvant setting;*

    b) *First-line therapy of metastatic breast cancer in hormone-refractory patients where anthracyclines are contra-indicated.*

2. The regimen with dosages and costs for a 1.8m^2 patient. Costs should include the costs of expected supporting medications e.g. anti-emetics and growth factors.
3. Cost per cycle and total cost of treatment plus cost including supporting treatment
4. A summary of available evidence supporting the application. All supporting data referred to in the summary should be attached.
5. A summary of the existing registered indications for the specific drug by the MCC, the FDA, and the European Regulatory Agency.
6. Package insert of the proposed product
7. Numbers needed to treat
8. Summary of budget impact assessment (analysis)
9. A brief summary of why patients need this treatment
10. Comparison between available treatment modality and the proposed treatment in terms of cost and clinical efficacy
11. Please indicate how the requested product should read in the guidelines
12. Is the product on EML and what is the Tender price?

Requirements for Submission

Regulatory approval: The therapy should be registered by the MCC, FDA and the European Regulatory Agency for the indication applied for.

Level of evidence: Level 1 evidence should be available and published. Where conflicting study results or controversy exists, this should be indicated and other supporting data providing "*proof of concept*" submitted e.g. the use of *taxanes* in adjuvant breast cancer. In exceptional cases showing clear and compelling benefit above the current standard of care, unpublished data e.g. major congress presentations, will be considered. In such instances the slides presented should be submitted, as well as supporting level 2 evidence.

Dated: 10/02/2016