ICON MEDICINE FORMULARY PROCESS

DISCLAIMER
The ICON Formulary process is an ethical and scientific cost sensitive exercise performed as described in this document.
ICON or Isimo do not have any influence over either the Formulary's implementation within a practice or practice specific product procurement.
ICON or Isimo do not regulate the choice of final product from those listed per class of medicine on the formulary.

INTRODUCTION

The Independent Clinical Oncology Network (ICON) is a provider of leading-edge specialist oncology services and solutions which result in measurable quality clinical and financial outcomes for patients and client schemes/funders. ICON has entrusted its operational functionality to ISIMO Health[1](www.isimo.co.za) to further its objectives of delivering quality care to patient.

ICON, through its healthcare management partner ISIMO, represents an innovation in managing the financial and clinical risk associated with oncology within any stated population within its care. This initiative emphasizes the integration and alignment between funder and provider objectives to the benefit of patients.

The ICON model relies on the following to achieve improvements in quality of care:

- A dedicated network of oncologists working in a structured way to standardize, monitor and continuously improve the patient-centered care process;
- Clinical Treatment Protocols that are evidence-based and stratified by treatment intent;
- A Medicine Formulary that supports the Treatment Protocols to ensure cost-containment to achieve a more equitable distribution of resources;
- A continuous improvement process of developing health systems (including IT and health outcomes) to meet the objectives of ICON.

[1] ISIMO is a healthcare company that improves the quality of patient care in South Africa, by aligning medical specialists and funders and applying proprietary evidence-based protocols and systems.

MEDICINE FORMULARY COMMITTEE

This Committee works in collaboration with the Treatment Plan Review Committee (TPRC). The latter committee of peers is responsible for the development and maintenance of the Clinical Treatment Protocols and for the authorization of out-of-protocol treatment and medicines.

The operational activities of the Formulary Committee are managed by the Operational Executive of ISIMO.

OBJECTIVES OF FORMULARY COMMITTEE:

- To review the appropriateness of the medicines on the Formulary;
- To remove medicines for safety, efficacy or cost reasons from the Formulary;
- To deal with any other issues related to the Formulary.

TIMELINES

- All medicines will be evaluated for inclusion in the formulary every 3 months.
- A new version of the Formulary will be released every 3 months.
- All applications (not new chemical entities, NCEs) must be received 1 month before the announced release date of the next formulary.
- All registered NCEs will be evaluated within 6 months of receipt of the application by the formulary committee. New and existing medicines for new indications may be referred to the TPRC for evaluation for inclusion in the protocol update which becomes effective at the beginning of the next calender year in line with medical schemes' benefit cycles. This time period also applies for the inclusion of medicines in the formulary as a result of a new indication of an existing medicine.
- An exemption to the above process will be considered in the following circumstances where:
    - The NCE makes a significant impact on clinical outcomes at a cost that is deemed affordable;
    - The NCE is less expensive than drugs within the same class that are already included in the protocol and formulary.
    - There is no generic of the medicine currently on the formulary and inclusion of such a generic medicine will result in huge cost savings.
    - There is a new formulation that greatly allows ease of administration of the medicine without significantly increasing financial burden.

Note:
For all exceptional cases an evidence-based approach should be followed. In all instances the benefit of including the medicine earlier on the formulary should be considered against waiting for the next update of the formulary. Some factors that will be considered are the frequency with which the medicine may be prescribed, the outcomes that may be achieved with the medicine, the cost savings as a result of the use of the medicine in the short term, etc. The medicines included in the formulary due to exceptional circumstances will be added to the formulary in the authorization system (e-Auth ®) and will not result in the re-distribution of the formulary to the

service providers or the pharmaceutical companies. A notice may be sent to the service providers indicating an addition to the formulary.

Any NCE that is deemed essential for inclusion into the Treatment Protocols before the new Treatment Protocols become effective, will be timeously communicated with motivation to contracted medical schemes:

- Explaining that the new addition with be less-expensive or cost-neutral;
- The clinical effectiveness is superior although at higher cost, but subject to out-of-protocol process.

RULES RELATING TO THE FORMULARY

The Committee will consider proposals that could facilitate greater equity in oncology care and this will form the basis for the process of inclusion of medicines in the Formulary.

Only Formulary medicines will be authorized without motivation by ICON. Non-formulary medicines will require a motivation from the treating oncologist and this should be submitted to the ICON TPRC for evaluation via the Out of Protocol (OOP) route.

POLICY GUIDELINES

Selection Criteria for inclusion in the formulary

The criteria and selection process for medicines to be included in the ICON Medicine Formulary will be periodically reviewed by the Formulary Committee. The process will be objective and evidence-based. The level of evidence submitted will be evaluated in line with the SORT Hierarchy of the levels of evidence. A high quality individual Randomized Clinical Trial (RCT) or a meta-analysis of similar RCTs will be considered to be good quality evidence.
The basic criteria include:

- Only medicines supporting the ICON Treatment Protocols will be considered;
- Medicines will be selected based on sound and adequate data of efficacy and safety available from clinical studies;
- Each selected medicine must be available in a dosage form in which adequate quality, including bioavailability and pharmaceutical equivalence, can be assured;
- Issues of stability under the anticipated conditions of storage and use will be considered;

- When two or more medicines appear to be similar in the above respects, the choice between them will be made on the basis of a careful evaluation of their relative efficacy, safety, quality, price and availability. Selected Formulary medicines in the formulations listed must be readily available nationally in the quantities required;

- The cost comparison between medicines will include the cost of the total treatment, and not only the unit cost of the medicine;

- The application for inclusion of a newly registered generic medicine where other similar medicines are already on the formulary will have to demonstrate, in addition to efficacy, safety and availability, also a significant price advantage over the medicine already on the formulary. Medicines that no longer demonstrate therapeutic value or 'value for money' will be removed from the formulary.

PRICING POLICY

A benchmark price is determined for a group of medicines with the same active ingredient. This benchmark price is the lowest price of a branded product within the group of medicines with a similar active ingredient. Currently, all medicines with that same active ingredient within 15% of the benchmark price will be included in the formulary. Where the cheapest product is not readily available this threshold will be readjusted in a transparent process where by the average or median cost of the lowest 3 products will be used as benchmark.

Temporary versus Permanent Price Reductions

Drugs with temporary price reductions will be listed on the e-Authorisation system and the ICON formulary if it is within 15% of the cheapest generic in its class and strength, but it will not be used as the baseline price, even if it is the cheapest. ICON only applies permanent prices as baseline when calculating whether a medicine is within the 15% margin.

If a drug price is reduced temporarily in between formulary releases, then the same principle as with permanent price reductions will apply i.e. it will only show on e-authorisation system if the temporary price reduction makes it cheapest in class and strength.

Drug supply issues

ICON has on occasion received complaints or information of certain medicines used in the management of oncology patients being out of stock or in short supply. We have engaged with pharmaceutical companies in an attempt to get them to alert us timeously of such issues. We would strongly urge all pharmaceutical companies to alert ICON promptly of any supply issues or information about a potential supply shortage or stoppage of a product. This will assist the oncology network practices in managing this problem. ICON reserves its right to consider the inclusion of a medicine on the ICON formulary based on the availability of medicines. ICON may

also request a stock guarantee from pharmaceutical companies as a criterion for inclusion of a medicine on the formulary.

ADDITIONS & DELETIONS

Any applications to add medicines or new formulations to the ICON Medicine Formulary (IMF) must be made in writing to ICON.

Application for Additions & Deletions can be submitted by any contracted ICON Oncologist or representatives from pharmaceutical companies.

(A) The application for GENERIC medicines for which another generic medicine or originator medicine is already currently on the formulary must contain the following information (unless otherwise stated). Information to be submitted electronically (via email) please:

- A signed covering letter
- Chemical name and Therapeutic class
- Trade name and supplier
- Unit price based on SEP
- Date of launch with information on stock availability
- The MCC approved package insert

(B) The application for GENERIC medicines for which another generic medicine or originator medicine is NOT currently on the formulary, the process described below for the Innovator medicines or bio-similars should be followed.
(This implies that the originator was probably not considered appropriate for inclusion in the formulary.)

(C) Applications for INNOVATOR MEDICINES OR BIOSIMILARS must contain the following information (unless otherwise stated):

- Applicant's name, Signature, Date
- A signed covering letter
- An executive summary
- Chemical name and Therapeutic class
- Trade name and supplier
- Unit price based on SEP
- Is this drug on the Essential Medicines List (EML) or Department of Health's Provincial Formulary?
  - If so, for which provinces?
- Registered indications for use
- Principal mode(s) of action
- Major adverse effects and drug interactions
- Precautions and contraindications

- Are there prescribing guidelines? Please attach and be specific as to point to relevant in and exclusion criteria as well as measurements for stopping or continuing treatment with timelines.
- Average dose and frequency
- Total daily dose
- **Average duration of therapy (stipulate maximum as well)**
- **Cost per cycle**
- **Cost for duration of treatment specifying the number of cycles**
- **Cost per benefit year**
- The MCC approved package insert
- A list of references used
- Evidence from the literature to support the inclusion on the formulary;.
- HTA within SA context.

The review of an application for innovator medicine or biosimilars for inclusion in the ICON protocols and formulary will incur a cost of R15 000 (excl).

The review of an application for generic medicine for inclusion in the ICON protocols and formulary will incur a cost of R3 000 (excl).

NOTE: This does not guarantee the inclusion on the medicine in the ICON protocols and formulary.

Applications for addition or deletion need to be submitted to**:**

ICON Formulary Committee
PO Box 15531
PANORAMA
7506

or submitted electronically to: formulary@cancernet.co.za

Reviewed: Dr Ernst Marais September 2016