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ICON FORMULARY PROCESS POLICY

DISCLAIMER
Icon does not influence the implementation of the Icon Formulary within a practice or practice-specific product procurement.
Icon does not regulate the choice of a product from those listed per class of medicines on the Icon Medicine Formulary

INTRODUCTION

Icon is a provider of specialist oncology professionals, programmes and services with the aim of improving clinical outcomes for cancer patients while being financially sustainable for the contracted schemes/funders.

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

- A country-wide network of oncologists
- Systems and structures that support this network
- Systems and structures that monitor and continuously improve patient access to quality care.
- Clinical Treatment Protocols that are evidence-based drawn up by the Icon provider network
- Clinical Treatment Protocols that are stratified by treatment intent.
- A Medicine Formulary that supports the Treatment Protocols
- Genericization of the Formulary to ensure cost-containment and increase patient access to treatment;

ICON FORMULARY COMMITTEE

The Icon Formulary Committee is constituted of clinical team members, clinical governance, and management. It works in collaboration with the Icon Treatment Plan Review Committee (TPRC). The TPRC is a committee of oncologists that is responsible for the ongoing updating and development of the Icon Clinical Treatment Protocols. The TPRC is responsible for the review of out-of- protocol treatment and medicines.

The operational activities of the Icon Formulary Committee are managed by the Executive of Icon Oncology Holdings.

OBJECTIVES OF FORMULARY COMMITTEE:

- To review the appropriateness of the medicines included on the Icon Formulary based on utility and cost
- To improve oncology medicine access for patients
- To remove medicines from the Icon Formulary for safety, efficacy or cost reasons

- To review new oncology medicines that are registered with the South African Health Products Regulatory Authority (SAHPRA)
- To deal with any other issues related to the Icon Formulary

TIMELINES

- All current Icon Formulary medicines will be re-evaluated for inclusion in the Formulary every 3 months.
- A new version of the Formulary will be released once a quarter.
- All applications for inclusion of existing medicines (this does not include new chemical entities (NCEs) or existing medicines with new indications) must be received 1 month prior to the announced release date of the next Formulary.
- All applications for inclusion of registered NCEs will be evaluated within 6 months of receipt of the application by the Formulary Committee and will be considered for inclusion in the Formulary at the first subsequent Formulary Committee meeting.
- All applications for inclusion of existing medicines with new indications will be evaluated within 6 months of receipt of the application by the Formulary Committee and will be considered for inclusion in the Formulary at the first subsequent Formulary Committee meeting.
- All applications for inclusion in the Icon Treatment Protocol for NCEs and existing medicines with new indications may be referred to the Formulary Committee and Icon TPRC for evaluation for inclusion in the Icon Treatment Protocol update. Any update becomes effective at the beginning of the next calendar year, in line with medical schemes' benefit cycles.
- All new entity applications submitted for consideration for the subsequent years' protocols, need to be submitted (Registered, SEP approved, review fee processed) by no later than 30 September each year. Agents submitted for review after this date will be prioritised for review at the discretion of the Icon Formulary Committee. Please note, agents submitted for review after this date are **unlikely** to be included in the subsequent years protocols as this fall outside protocol publication and / or scheme benefit engagement timelines. These agents, however, will be available for selection on the eAuth platform and subject to Out of Protocol review.
- 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 a significant cost saving

- There is a new formulation that significantly allows ease of administration of the medicine without significant cost implications

Note:
For all exceptional cases, an evidence-based approach will be followed. The benefit of earlier inclusion of a medicine on the Formulary will be weighed up against the negatives of delaying inclusion until 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

Any NCE that is deemed essential for inclusion into the Treatment Protocols before the new Treatment Protocols become effective, will be timeously communicated with the requisite motivation to contracted medical schemes in relation to the:
- Clinical benefit
- Financial impact

RULES RELATING TO THE FORMULARY
The Committee will consider proposals that could facilitate greater equity in oncology care. This will form the basis for the process of the inclusion of medicines in the Formulary.

Only Formulary medicines will be available for authorisation via eAuth® without motivation. Non-Formulary medicines will require a motivation from the treating oncologist. This must be submitted to the Icon TPRC for evaluation via the Out of Protocol (OOP) eAuth® 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 and updated by the Icon 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. High-quality Randomized Clinical Trials (RCT) or meta-analyses of similar RCTs will be considered to be good quality evidence.

The basic criteria for inclusion of a medicine on the Icon Formulary are:
- Medicines that are part of the Icon Treatment Protocols
- Medicines with adequate and sound data of efficacy and safety

- Medicines that are available in a dosage form in which adequate quality, including bioavailability and pharmaceutical equivalence can be assured
- Medicines that have demonstrated stability under the anticipated local conditions of storage and use

Decisions of the choice of a medicine for inclusion on the Formulary will also depend on:

- The relative efficacy, safety, quality, price and availability of two or more medicines that are similar in all the above respects
- Sufficient stock of a medicine in the formulations listed at quantities required for seamless national availability
- The comparative cost calculations of medicines. This will include the cost of the total treatment and not only the unit cost of the medicine
- For a newly registered generic medicine where other similar medicines are already on the Formulary, the application for inclusion will have to demonstrate, in addition to efficacy, safety and availability, a significant price advantage over the medicine already on the Formulary.

PRICING POLICY

Benchmark Price

The benchmark price will be determined for a group of medicines with the same active ingredient and formulation.

This benchmark price is the lowest price of a branded product within the group of medicines with a similar active ingredient that adheres to the policy guidelines above.

All medicines with the same active ingredient and within 15% of the benchmark price will be included in the Formulary.

EXCEPTIONS

1. Different Product Strengths

Where one product strength is in-formulary and the other product strength is >15% of the benchmark price, the second strength may be considered for inclusion in the Formulary for combination purposes, after careful consideration and at the discretion of the Formulary Committee.

2. Discontinued or long-term OOS*

The Icon Formulary Committee reserves the right to consider the inclusion or exclusion of a medicine on the Icon Formulary based on the availability. Icon may remove a medicine from the Formulary and e-Auth® system if there is evidence of inconsistent stock and/or supply issues.

The Committee may also request a stock guarantee from pharmaceutical companies as a criterion for inclusion of a medicine on the Formulary.
Where the cheapest product is not readily available, the threshold will be readjusted in a transparent process whereby the average or median cost of the lowest 3 products will be used as benchmark.

3. Price changes mid-formulary release

(i) Pricing reduction resulting in medicine being cheapest in class

If a medicine becomes cheapest in class during Formulary releases, it will be added to the Icon Formulary in the authorization system (e-Auth ®) but will not result in the re-distribution of the Formulary to the service providers or the pharmaceutical companies, or a change in the listed current formulary medications. The subsequent formulary will be updated accordingly, and a notice will be sent to the service providers indicating an addition to the Formulary.

(ii) Price reduction resulting in medicine being within 15% of benchmark price

If a medicine falls within 15% of the benchmark price, but is not the cheapest in class, during formulary releases, it will not be added to the Icon Formulary in the authorization system (e-Auth®). It will, however, be available in the non-Icon Formulary and subject to Out of Protocol review by the TPRC. The subsequent Formulary will be updated accordingly.

4. Temporary versus Permanent Price Reductions

(i) Temporary price reductions will not influence benchmark pricing. Icon will only apply a permanent price as the baseline or benchmark product. If a drug price is reduced temporarily between Formulary releases, the same principle as with permanent price reductions above will apply, i.e. it will only show on the e-Auth® system if the temporary price reduction makes it cheapest in class, formulation and strength.

(ii) For any product included on the Icon Medicine Formulary based on a temporary price reduction, and a significant increase in the price occurs between published formularies, the product will be removed from e-Auth® system at the discretion of the Formulary Committee.

5. Unregistered (Section21) and Compassionate-use medicines

These medicines are exempt from SEP (unregulated) and do not appear on the Icon Medicine Formulary. In the event of the discontinuation or long-term stock outage of a registered medicine that is on the Icon Treatment Protocol, a suitable section 21 replacement will be considered for inclusion on the Icon Medicine Formulary, at the discretion of the Formulary Committee.

6. Continuation of non-formulary treatment

For non-Icon patients who become Icon patients due to transfer of care, and who have already been established on a non-Formulary medicine, application for continuation of the said medication may be reasonably granted and is subject to review as an out of protocol request by the TPRC.

7. Serious adverse events*

In the instance where a medicine no longer demonstrates acceptable safety, and where this medication is under investigation by the MCC, this medication will be removed from the Formulary, while pending investigation, at the discretion of the Icon Formulary Committee.

* Medicines that no longer demonstrate acceptable safety, therapeutic value or 'value for money', stability or sufficient stock nationally will be removed from the Formulary at the discretion of the Icon Formulary Committee.

8. Single available agents on Formulary

In the instance where no alternative products in a class of medicines fall within 15% of the benchmark price, only that medicine will appear on the formulary. All the medicines in such a group not within 15% of the benchmark price will be excluded in the Formulary, as per normal processes. If, however, there are concerns regarding stock supply, the next cheapest medicine in that class may be included

9. Permanent significant price reductions

Significant permanent price reductions may potentially impact the placement of a product within the Clinical Protocols between protocol publications. Decision to review a product in the setting of a significant and permanent price reduction is at the discretion of the Icon Formulary Committee and Clinical Protocols Review Committee. A benchmark of at least 30% reduction in cost, which results in a meaningful reduction in cost, and where there is an identified unmet clinical need, would be required to qualify for consideration of review. No review fee will be charged in this setting.

NB. The Icon Formulary Committee strongly urge pharmaceutical companies to alert us promptly of any safety or supply issues or information about a potential supply shortage or stoppage of a product. This will assist Icon in alerting Icon network practices timeously to these issues and so prevent potential harm to patients.

ADDITIONS & DELETIONS OF MEDICINES

Any applications to add medicines or new formulations to the Icon Formulary 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 (multisource) 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
- Therapeutic class
- Trade name
- Supplier name
- Unit price based on SEP (both inclusive and exclusive of VAT)
- Date of launch with information on stock availability
- The MCC approved package insert

(B) The application for GENERIC medicines for which another multisource generic medicine or originator medicine is NOT currently on the Formulary, the process described below for the Innovator medicines or bio-similar 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

- Therapeutic class
- Trade name
- Supplier name
- Unit price based on SEP both inclusive and exclusive of VAT
- Details of Essential Medicines List (EML) listing or Department of Health's Provincial Formulary listing
    - If so, for which provinces?
- Registered indications for use
- Principal mode(s) of action
- Major adverse effects and drug interactions
- Precautions and contraindications
- Prescribing guidelines with both inclusion and exclusion criteria with specific 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 Icon Formulary
- HTA within SA context.

(D) Review fees for inclusion into the Icon Protocols and Formulary:

The review of an application for an innovator medicine for inclusion in the Icon protocols and Formulary

- **Basic cost of R53 500 (excl. VAT).**
- **Additional quotation based on complexity of analysis.**

The review of an application for a biosimilar for inclusion in the Icon protocols and Formulary

- **Basic cost of R10 700 (excl. VAT).**
- **Additional quotation based on complexity of analysis.**

The review of an application for a biosimilar or innovator medicine, already included in the Icon Treatment Protocols, but with the intention of reviewing the placement of the product within the Icon Treatment Protocols (i.e., movement from Enhanced placement to Core placement), in the absence of a change in price or new evidence

- **Basic cost of R10 700(excl. VAT).**
- **Additional quotation based on complexity of analysis.**

Please note, applications for review of placement within the Icon Treatment protocols will only be considered if there is new evidence for submission, or if there has been a change in unit price.

The review of an application for generic (multisource) medicine for inclusion in the Icon protocols and Formulary:

- **Basic cost of R5 350 (excl. VAT).**

NOTE: Product review does not guarantee the inclusion of the medicine in the Icon treatment protocols and formulary as this is a processing fee only.

Product reviews are discussed quarterly by the Icon Formulary Committee, and only those for which payment has been received in full by the stipulated date will be considered for discussion at this forum.

APPEALLING THE DECISION FROM THE ICON FORMULARY COMMITTEE:

(E) Appeal for placement in the Icon Treatment protocols in the setting of **new evidence (i.e. necessitates a full revision of the HTA);**

- **Basic cost of R53 500 (excl. VAT).**
- **Additional quotation based on complexity of analysis.**

(F) Appeal for placement in the Icon Treatment protocols **in the absence of new evidence.**

- **Basic cost of R10 700 (excl. VAT).**

(G) Appeal for placement in the Icon Treatment protocols in the setting of **a change in price.**

- **Basic cost of R 5 350 (excl. VAT).**

Applications for addition or deletion need to be submitted to: Icon Formulary Committee;
PO Box 5098, Tygervalley, 7536.

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

Reviewed: Dr David Eedes March 2018

Updated: Belinda Bailey March 2019
Updated: Formulary Committee team July 2019
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