Policy Name: **Formulary Management**			
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1.0 Change of policy

1.1 No changes

2.0 Purpose

2.1 The goal of the formulary management is to manage medications to offer safe, cost- effective and beneficial outcomes for patients, and supports an affordable and sustainable drug benefit program at CCHE. The formulary management is managed by PNT Committee which establishes and implements policies regarding selection and use of drugs, therapies and identify those that are most medically appropriate, safe and cost effective to best serve the health.

3.0 Policy

3.1 Policy statement:

3.1.1 Formulary management is an integrated patient care process which enables physicians, pharmacists and other health care professionals to work together to promote clinically sound, cost-effective medication therapy and positive therapeutic outcomes.

3.2 Scope:

3.2.1 Formulary management covers medications that are approved by PNT, these medications established clinical value and do not represent a duplication of therapeutic effect.

3.3 Responsibilities

3.3.1 Medical Director

3.3.2 Head of pediatric Oncology

3.3.3 Pharmacy Director

Classified	Control Stamp		Page: 1 of 5

3.3.4   Pharmacists

3.3.5   The PNT Committee

3.3.6   Supply chain manager

3.3.7   Planning section head

3.3.8   Physicians

3.3.9   Pharmacists

4.0   Definitions /abbreviations:

4.1   CCHE: Children Cancer Hospital - 57357 Egypt

4.2   MMU: Medication Management & Use

4.3   MMS: Medication Management & Safety

4.4   PNT committee: Pharmacy, Nutrition and Therapeutics Committee.

4.5   Formulary system: A system of periodically evaluating and selecting medicines for the formulary, maintaining the formulary, and providing information in a suitable manual or list**.**

4.6   Formulary medication: A list of medicines approved for use in the healthcare system by authorized prescribers.

4.7   MOH: Ministry of Health.

4.8   DPS: Department of Pharmaceutical Services.

4.9   FDA: Food Drug Administration.

4.10   EMEA: European Medicines Evaluation Agency

4.11   PI: Principal Investigator.

4.12   A reference country: USA, Canada, Western European countries, Australia.

4.13   Restricted Formulary Drugs: Formulary drugs may be restricted in their use, either by (1) medical service, (2) prescribing criteria or (3) patient care area (4) Administration limitations.

4.14   DIC: Drug Information Center.

4.15   MISK (Medical Informatics Saving Kids): HIS of CCHE

4.16   BUD: Beyond Use Data.

4.17   Oracle fusion system: The Supply Chain information system in CCHE

5.0   Procedure:

5.1   PNT role in formulary management system:

5.1.1   The PNT Committee is responsible for all matters related to the use of medication as its overseeing the effective and efficient use of medication and assist in generating policies relating to medication use in the hospital, including their evaluation,selection, procurement, storage, distribution, administration.

5.1.2   The committee usually consists of healthcare providers involved in prescribing, dispensing, and administering medications.

5.1.3   The PNT committee reviews and updates the hospital formulary every year and medication are included in the formulary by their generic names.

5.1.4 Medication are prescribed by generic names as physician are strongly encouraged to prescribe medication by generic name.

5.1.5 The PNT committee should systematically address medication and patient safety issues and ensure that medication-use policies adequately address potential risk and safety issues.

5.2 PNT Approval Criteria:

5.2.1 Drugs included in the hospital's formulary should be approved for use by the MOH.

5.2.2 Anticancer drugs preferable to be FDA approved or EMEA approved by its trade name.

5.2.3 If that condition (5.2.2) is unavailable in marketed drugs, MOH approval for alternatives (approved Trades) will be approved.

5.3 Formulary Addition and Deletion:

5.3.1 Attending physicians or pharmacists may request drugs to be added to or deleted from the formulary by completing a Formulary Addition request form due to below reasons: -

 5.3.1.1 Repeated shortages may be trigger for formulary additions or deletions.

 5.3.1.2 In case of a new Protocol or Guidelines or any modifications requiring the use of new medication

 5.3.1.3 In case of launching new medication

5.3.2 PNT review addition request based on below

 5.3.2.1 Addition justification

 5.3.2.2 Approved alternative available

 5.3.2.3 Efficacy and effectiveness

 5.3.2.4 Cost effectiveness

 5.3.2.5 Adverse effect

 5.3.2.6 Preparation issues

 5.3.2.7 Sound-alike or look-alike potential.

 5.3.2.8 Dosing or administration issues.

5.3.3 When a drug is added to the formulary, consideration must be taken to delete alternative if there is need for that.

5.3.4 Criteria for medication deletion: -

 5.3.4.1 MOH recalls

 5.3.4.2 Addition of new alternatives

 5.3.4.3 Formulary review reports

5.4 Purchasing:

5.4.1 Purchasing of routine medications (Formulary medications):

 5.4.1.1 Planning manager generates purchasing request through oracle fusion system either by tender or monthly orders based on average monthly consumption.

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5.4.1.2 Planning manager generates medication purchasing orders according to Hospital Item Ordering, Processing and Monitoring policy.

5.4.1.3 Purchasing department generates Purchasing order to companies.

5.4.1.4 Purchasing formulary medications from pharmacies is only permitted in case of unavailability (critical shortage) of medications or substitutions in companies which are approved by PNT committee.

5.4.1.5 Formal communication must be sent to companies by purchasing department before purchasing any items from pharmacies.

5.5   Receiving Medications and storage:

5.5.1   Refer to Medications storage policy.

5.6   Physician Ordering and transcription:

5.6.1   Physicians should order medications by generic names as listed in the hospital formulary.

5.6.2   The pharmacy will be responsible for maintaining an inventory of those drugs currently listed in the hospital formulary.

5.6.3   **Ordering of Non formulary drugs**

5.6.3.1 In general, only those agents listed in the hospital formulary should be prescribed. A physician may order a non-formulary medication for a particular patient, if necessary.

5.6.3.2 When physician prescribe a non-formulary medication The pharmacist informs the physician that the medication is non-formulary medication and inform him with other formulary alternatives available.

5.6.3.3 If the physician accepts the alternative formulary drug, the drug is dispensed to the patient upon prescription as per hospital policies

5.6.3.4 If the alternative not accepted by physician or no available alternative in hospital formulary "Non-Formulary Drug Request form is sent to the pharmacy

5.6.3.5 Any non-formulary medication will be coded in MISK and oracle system under non formulary category.

5.6.3.6 Physicians should be aware that there may be a time delay because the pharmacy often must procure the drug from outside the hospital

5.6.3.7 Pharmacy generates purchase order in oracle fusion system (per patient purchase request) which will be as following:

5.6.3.8 Life saving per patient : Fast track (same day purchase request): direct to purchase department.

5.6.3.9 Chemotherapy : ordered from combined clinic, it will be ordered monthly and semi monthly to cover 2 – 3 cycle according to patient case and it's not permitted to be repeated without a new combined clinic

5.6.3.10   Multispecialty medication ordered semi monthly to cover 2 – 3 months according to patient case

5.6.3.11   If there is need to add any non formularly medication it will be reviewed with PNT

5.6.4 **If PNT committee approves the addition of a new drug:**

5.6.4.1 The medication will be introduced to MISK and oracle fusion system as formulary medication

5.6.4.2 DIC pharmacist and Decision Support (Internal Audit Pharmacist) is responsible for reviewing the newly added medication information reference and informing DPS IT Co-coordinator with any required MISK special database information (IV order sets, Dose Bands, min Dilution, max doses, BUD, Clinical Alerts and any other relevant Drug information) that required in HIS.

5.6.4.3 Decision support (Internal Audit pharmacist) review required medication labeling (High alert, hazardous, LASA).

5.6.4.4 Study team PI and pharmacy team are responsible for the development of any required restricted orders/ preprinted orders to be available in the hospital.

5.7 **Monitoring New Drug Usage and outcomes:**

5.7.1   The new drug added to formulary will be under evaluation and any reports from the healthcare team members will be sent to the DPS director, a New Drug Use Evaluation report will be introduced by the pharmacy to the PNT.

5.7.2   Report is then presented to PNT Committee for Evaluation and Decision Making.

5.8 **4.8 Annual Formulary Review:**

5.8.1   The formulary is reviewed annually by PNT.

5.9 **5.0 Formulary availability:**

5.9.1   5.1 the formulary is available on DMS as a searchable database

6.0   References:

6.1   N/A

7.0   Appendices:

7.1   **Related Forms:**

7.1.1   Formulary Addition Request Form

7.2   **Related Policy(S):**

7.2.1   Medication Management Program

7.3   **Related Standards:**

7.3.1   JCI standards 7th edition – MMU Chapter.

7.3.2   GAHAR Standards name. MMS.03

7.4   **Attachments**

7.4.1   CCHE Formulary List