**Standard Operating Procedure for Formulary Additions to a System P&T Formulary**

**Purpose:** This SOP outlines the process for adding medications to the System Pharmacy and Therapeutics (P&T) formulary to ensure that all additions are based on objective, scientific data and align with the health system's goals of safety, efficacy, and cost-effectiveness.

**Scope:** This procedure applies to all prescribers, pharmacists, and members of the P&T Committee within the health system.

**Definitions:**

**System Formulary:** A list of medications approved for use within the health system.

**Facility Formulary:** A smaller subset of the System Formulary for use at a local market hospital. The Facility Formulary may be more restrictive, but it shall not be less restrictive than the System Formulary.

**System P&T Committee:** the committee responsible for evaluating and approving medications for inclusion in the system formulary.

**Local P&T Committee:** committee responsible for reviewing System P&T decisions and may act to be more restrictive on the facility formulary. The Local P&T Committee does not have the authority to add medications to the system formulary. Key functions of the local P&T Committee should include:

System P&T Formulary Decisions:

* Approved – medication will be formulary for the health system, but may remain non-formulary at some facilities
* Provisionally approved – approved temporarily for system formulary with a scheduled review of specific data as defined by the System P&T Committee
* Restricted – Formulary items may be formulary only for specified indications or for patients who meet specified criteria
* Not approved – medication will be non-formulary at all facilities

**Responsibilities:**

**Clinical Lead:** Responsible for discussing formulary changes and drug monographs with the formulary management committee.

**Pharmacy Department:** Responsible ensuring decisions made by the System P&T and Local P&T are executed and are responsible for dispensing medications based on the formulary.

**System P&T Committee:** Responsible for reviewing and approving formulary additions.

Physicians – responsible for completing formulary request forms and presenting formulary request to System P&T Committee

**Procedure:**

**Request Submission:**

Physicians may request the addition of a medication to the formulary by completing a formulary addition request form.

The request form should include objective, scientific data on the medication's effectiveness, side effect profile, cost, medication error potential, and comparison to alternative agents.

Before being presented at System P&T for review, the requesting provider MUST either having approval from their respective Service Line Group or receive an exemption from the P&T chair.

***Key Point****: under no circumstances should formulary addition forms be provided to or filled out by a Pharmaceutical Representative.*

**Initial Review:**

The Multifacility Clinical Pharmacy Group (MFCPG) reviews the request and makes an initial recommendation on whether the medication is appropriate for addition to the System Formulary based on objective, scientific data as well as cost, reimbursement, and comparison to alternative formulary agents.

**System P&T Committee Review:**

The Clinical Lead will present the drug monograph to the P&T Committee for discussion. The Physician who submitted the Formulary Addition Form should present their request, indication, and literature supporting the request to add to formulary. A physician may delegate this task to another party with prior approval by the P&T Committee Chair.

The P&T Committee evaluates the medication based on safety, efficacy, and cost-effectiveness.

**Special considerations:**

* **Labor Productivity:** Other considerations include the impact the medication could or would have on a specific department or departments. If it is determined that the use of the medication will lead to the need to be added to a specific department or departments to accommodate the administration of the medication, it will automatically be expected that the physician requesting champion the projected changes in workflow and staffing. It will be immediately referred to the Performance Improvement team and senior leadership at the affected facility will be included for line of sight. Once implemented, a follow-up presentation will be expected to be presented to the System P&T on the outcomes of the project.
* **Reimbursement:**
* **J Code:** any outpatient medication that does not have an assigned J code will not be added to the formulary without a pathway for reimbursement.
* **Other:** after financial review, if it is determined that the cost of the medication exceeds the expected reimbursement the drug request will be provisional denied and the high cost drug policy and procedure should be followed.

**Approval and Implementation:**

If approved, the medication is added to the formulary, and consideration is given to deleting other items to maintain a balanced formulary.

The Pharmacy Department is expected to update the formulary list after the meeting and ensures that the medication is available for dispensing as soon as possible, but within 60 days.

If the medication has potential for adverse reactions or high cost, it may be provisionally approved for a limited time frame (maximum of 12 months), with a medication use evaluation performed at the end of the period.

Medications may be approved for formulary with restrictions to specific indications or specific patient populations. Physicians and other prescribers should utilize restricted formulary medications only within the approved restrictions, however, if the need arises outside of the approved restrictions, the non-formulary request process should be followed. If use outside of the currently approved restriction criteria occurs frequently, the physician should submit a formulary appeal form for review of the restrictions.

If the medication is added to the formulary, provisionally approved, approved with restrictions, or rejected, the provider will receive a letter with the System P&T’s decision with any related restrictions or provisions. If rejected, the decision may be appealed directly to the Local Medical Executive Committee.

**Provisional Reviews:**

Any medications provisionally approved for system formulary by the committee shall require a specific time frame for the provisional approval at the end of which a medication use evaluation will be performed. The results of the medication use evaluation will be presented to local P&T and reported back to system P&T. Areas of non-compliance should be addressed with corrective action plans assigned to the Chief Medical Officer of the local facility. If non-compliance with provisional acceptance or if outcomes data do not support the continued use of the medication, approve could be revoked by the system P&T committee.

**Annual Review:**

The MFCG conducts an annual review of the formulary, using class reviews, monographs, and primary literature to make recommendations for additions, removals, or updates.

Any changes to the original recommendations are added to the next available System P&T agenda for review, discussion, and vote, if the Committee Chair determines a vote is necessary.

Medications previously reviewed by System P&T that were not approved for formulary shall not be re-reviewed for formulary approval until a minimum of 12 months have passed or new, compelling data has been published; whichever is shortest.

**Documentation:**

All formulary additions, deletions, and updates must be documented in the P&T Committee meeting minutes and the official system formulary list. Local facilities are responsible for updating local formulary lists.