# Formulary Request Considerations

## Hospital Formulary

A hospital formulary is a list of medications stocked by the hospital pharmacy and related information for prescribing. Not all medications are on formulary, but comparable drugs may be available.

## Pharmacy & Therapeutics Committee[1,2]

The Pharmacy & Therapeutics (P&T) committee members include staff physicians, pharmacists, advanced practice professionals, nurses, administrators, and other healthcare professionals. The P&T committee reviews drugs for inclusion on formulary, and give consideration to the medication's effectiveness, cost, and indication for the facility's patient population and co-morbidities.

## Formulary Kit

The pharmaceutical manufacturer often develops a Formulary Kit for your reference that provides a review of the medication and may be used to engage others in the discussion prior to submitting a request for addition to formulary. The formulary kit provides information on clinical studies, medication description, clinical pharmacology, indications and usage, contraindications, warnings and precautions, adverse reactions, overdose, dosage and administration, how supplied, and other important safety information.

## AMCP *Format for Formulary Submissions*[3]

The Academy of Managed Care Pharmacy (AMCP) *Format for Formulary Submissions* provides a framework to advise drug manufacturers regarding important health care decision maker (HCDM) evidence requirements as it relates to evaluating new technologies for formulary consideration. The *Format* offers considerations related to fostering rigorous, relevant, and ongoing scientific dialogue between manufacturers and HCDMs across the product cycle as new evidence becomes available related to assessing the safety, efficacy, and value of new health technologies. The *Format* provides considerations for biosimilars, medical devices, comparative effectiveness research, and companion diagnostic tests, to name a few.

The evidence requirements outlined in the AMCP *Format* are intended for use by manufacturers who are responding to an unsolicited request from HCDMs to support coverage, reimbursement, and/or formulary placement of new and existing drugs, tests, or devices or class of drugs, tests, or devices.

The *Format* supports the informed selection of drugs, tests, and devices by:

- Identifying the evidence required for evaluating the clinical and economic value of drugs, companion diagnostic tests, and devices
- Standardizing the synthesis and organization of the evidence in a concise document also known as the "AMCP dossier" or "product dossier"
- Providing the manufacturer the opportunity to communicate the value of a product that is grounded in evidence-based medicine principles



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- Supporting the FDA's established unsolicited request process that manufacturers must abide by in order to provide comprehensive information that goes beyond a product's FDA-approved label
- Requiring economic models and projections of product impact on the organization and its enrolled population
- Encouraging a clear, transparent, and two-way communication process between manufacturers and HCDMs

**Request Elements**

- Name of requestor(s)
- Specialty area of practice
- Trade name of requested drug
- Generic name of requested drug
- Therapeutic category
- Manufacturer(s)
- Dosage form(s) available for requested drug
- Strengths available for requested drug
- Comparable drug(s) on Formulary
    - Is it more efficacious than other formulary drugs?
    - Is it more/less toxic than other formulary drugs? Are there any other special cautions or side effects?
    - Is it more/less costly than other formulary drugs?
    - Is it more/less cost-effective in lowering overall health care costs?
- FDA approved indications for use, clinical indications and/or standard of care
    - Inclusion criteria
    - Monitoring for adverse drug reactions/interactions, and preventative and/or management of each
- Mechanism of action
- Supporting references and/or clinical literature. Related bibliography and copies of two pivotal studies from peer-reviewed literature that demonstrates superiority of this agent over others. Randomized controlled trials comparing the drug to other drugs used to treat the same disease states are preferred.
- Situations when the drug is more effective/superior to the medications on the Formulary
- Which drug(s) could be removed from the Formulary?
- Special risks, cautions and restrictions in use
- Special patient safety considerations (e.g., look alike, sound alike)
- Anticipated frequency of use of requested drug in practice in the next 6 months
    - Number of patients
        - Inpatient
        - Outpatient
- Expected cost per patient admission
- Outcome measures to determine drug efficacy
- Potential conflicts of interest
    - I have received support from the manufacturer of the product Yes No
    - I have a consulting agreement with the manufacturer of the product Yes No
    - I, my spouse or partner, or a dependent, have a financial interest in the manufacturer of the product. Yes No



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- Considerations
- Attending physician on staff or Director of Pharmacy may request addition to the medication formulary. Chair or Chief approval may be required
- Pharmacy and Therapeutics Committee (P&T) or similar committee may require 4-6 weeks prior to next scheduled meeting to develop assessment for consideration.
- Identify leaders
    - Physician(s)
    - Director of Pharmacy, related clinical pharmacist
    - Director of Nursing
        - Will medication administration policy need to be modified for RN or others to administer
        - Are there staff license, education and competency concerns? (cost to educate)
    - Other professionals
- P&T Committee Presentation
    - Department of Pharmacy will present medication monograph
    - Requestor will provide additional information, if applicable
    - Discussion between P&T Committee members, Department of Pharmacy and requestor.
    - Requestor is excused for committee discussion to make motion

**References**


1. World Health Organization. Drug and Therapeutics Committee – A Practical Guide. 2003. http://apps.who.int/medicinedocs/en/d/Js4882e/5.2.html
2. Institute for Safe Medication Practices. The truth about hospital formularies. Survey shows many myths still exist 15 years later. *Acute Care ISMP Medication Safety Alert!* February 10, 2005 http://www.ismp.org/newsletters/acutecare/articles/20050210.asp
3. Academy of Managed Care Pharmacy. The AMCP Format for Formulary Submissions. Version 4.0, April 2016 http://www.amcp.org/practice-resources/amcp-format-formulary-submissions/


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