Duke Medicine
Request for Utilization of a Non-FDA Approved Drug

Instructions:
The Duke University Hospital (DUH) Center for Medication Policy, P & T Committee Chair, and P & T Committee Secretary consider requests for non-FDA approved drugs to be used within DUH. For the purposes of this form, non-FDA approved drugs are agents which have not yet been approved/deemed to be safe and efficacious for any indication by the FDA. The data concerning efficacy, safety, tolerability, and cost of an agent will all be considered when determining whether or not it is appropriate to be used at DUH. The Chair of the DUH P & T Committee will make the final decision on whether or not use of the non-FDA approved drug is appropriate.

Please fill out this form completely. This form consists of two parts: Part A – Request for Drug Utilization and Part B – Conflict of Interest Disclosure. You must be an attending-level physician to request a non-FDA approved drug to be used in patients at Duke University Hospital. Additionally, the Physician Chair of the Pharmacy & Therapeutics Committee must countersign this form. Forms that are submitted without the appropriate signatures will be returned to the requester. Please send the completed form via one of the following mechanisms:

Duke Center for Medication Policy
Department of Pharmacy
Duke University Hospital
14221 Trent Drive/Box 3089
Telephone: 919-684-5125 Fax: 919-613-7830
Email: ann.scates@duke.edu

Part A – Request for Drug Utilization

Generic name: _________________________________________________________
Trade name: __________________________________________________________
Manufacturer: __________________________________________________________
Other nations (if any) where drug is approved: ______________________________
Indication(s) __________________________________________________________
Dosage form(s) and strength(s) requested for use at DUH: ______________________

Why is this medication superior to or significantly better than current formulary agents?

_____ Improved Safety Profile  _____ Improved Efficacy  _____ More Convenient Dosing Regimen

_____ Less Prone to Med Errors  _____ Additional Indications  _____ More Cost Effective

_____ Other (Please Explain): ______________________________________________
Based on the above information, please provide the literature citations to support use in patients at DUH. If this is an EAP, please submit protocol, informed consents, pharmacy manual and/or investigator brochure.

What indication(s) do you intend to use this medication for?

Please provide any additional information you think pertinent to assist in evaluating this agent for utilization at DUH.

Were you involved in the clinical trials for the medications?  

_____Yes  

_____No

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Part B – Conflict of Interest Disclosure

Note: This information is considered when evaluating your request. A potential conflict of interest does not preclude a person from requesting a non-FDA approved medication for utilization. Duke University Hospital appreciates that physicians with an area of expertise often receive research grants or other support from industry. Duke University Hospital considers it important to disclose these relationships to eliminate any concerns regarding potential conflicts of interest. Please provide the following information to the best of your knowledge:

Companies involved in the development, production and distribution of the requested medication:

Do you, or an immediate member of your family, have a proprietary interest in any of these companies listed?  

_____Yes  

_____No  

If yes, which companies?

Please check all that apply:

_____ Own stock in one of the above companies (excluding mutual funds).

_____ Serve on the Board of Directors for one of these companies.

_____ Expect to receive (or currently receive) royalties from one of these companies.

_____ Other:  

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Have you received any financial support in the last 12 months from the companies listed?
______Yes  ______No  If Yes, which companies?
____________________________________________________________________________________
______

Please check all that apply:
______ Received more than $5000 in research funding.
______ Received support for presenting continuing education or professional education programs supported by the company (defined as more than 1 lecture for the same company in a 12-month period).
______ Received an educational grant of more than $5000.
______ Received more than $500 in travel support, personal gifts, compensation, or rewards in the past 12 months.
______ Other: ________________________________________________________________

Requester’s name and specialty (Please Print):
______________________________________________________________

Requester’s signature: ________________________________
Pager# ________

Pharmacy & Therapeutics Committee Physician Chair signature: ________________________
Pager# ________

Date Form Completed:____/____/______