# Policies Governing the Partners Pharmacy and Therapeutics Committee

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1. ORGANIZATION AND STRUCTURE

Figure 1: Organization and structure of the Partners Pharmacy & Therapeutics Committee

1.1. Partners Pharmacy & Therapeutics Committee (PPTC)

- The PPTC will serve as the decision-making body and advisory panel to Partners medical, pharmacy and nursing leaders on formulary management.
- The Chief Clinical Officer will appoint a physician Chair and a pharmacist Vice-Chair; the appointment will be re-evaluated after three years by the Chief Clinical Officer in consultation with Partners leadership.
- The Committee will be multidisciplinary and will include local organization Pharmacy & Therapeutics (P&T) chairs, Chief Pharmacy Officers, as well as representatives from medicine, pharmacy, nursing, quality/safety, finance, risk management and others as deemed necessary (Appendix 1). Total membership will not exceed 35 individuals.
- Non-P&T Chair and non-Chief Pharmacy Officers members will be appointed by local organization leadership who will determine term duration but this will not be less than three years.
- Members must attend 75% of meetings per year; failure to do so may result in termination from the PPTC.
• Members shall have an established alternate designee to attend meetings in cases of their absence. Selection of an alternate is left to the discretion of the PPTC member; however, the designee should have expertise in P&T processes and formulary decision making.
• Ad hoc members and guests may be invited to attend meetings as deemed appropriate by the Chair and Vice-Chair.
  o Ad hoc members and guests must recuse themselves from executive sessions when deemed appropriate

1.2. Subcommittees
• Specialty Sub-Cs will be developed. Select specialty Sub-Cs (e.g. Oncology and Ambulatory Pharmacy) will be standing committees while others will convene on an ad hoc basis.
• Specialty Sub-Cs will serve as clinical advisors to the PPTC. The Sub-C will provide recommendations to the PPTC on formulary decisions and other medication-related issues as deemed appropriate.
• The Sub-Cs will be multidisciplinary and will include physicians, pharmacists, nurses, and other healthcare professionals with expertise in a specific clinical specialty. Membership will not exceed 30 individuals per Sub-C (Appendix 1).
• Members of the Specialty Sub-Cs will be appointed by local organization leadership who will determine term duration but will be no less than three years.
• The Chief Clinical Officer will appoint a physician Chair and a pharmacist Vice-Chair for the standing Sub-Cs; the appointment will be re-evaluated after three years by the Chief Clinical Officer in consultation with Partners leadership. The election of a Chair and Vice Chair will be left to the discretion of the ad hoc Sub-Cs.
• Members must attend 75% of meetings per year; failure to do so may result in termination from the Sub-C.
• Members shall have an established alternate designee to attend meetings in cases of their absence. Selection of an alternate is left to the discretion of the Sub-C member; however, the designee should have expertise in P&T processes and formulary decision making.
• Ad hoc members may be invited to attend meetings as deemed appropriate by the Sub-C.

1.2.1. Oncology Subcommittee
• This Sub-C will utilize expertise of multidisciplinary oncology experts to provide stewardship of oncology medications across the system.
• The oncology Sub-C will provide recommendations to the PPTC for oncology formulary decisions, which may include formulary modifications, treatment guidelines/algorithms, and medication use evaluations as deemed appropriate.
• Materials that may be reviewed and approved by this Sub-C that do not require approval by the PPTC include:
  o New indications for existing drugs on formulary
  o Formulary reviews for oral chemotherapy medications
  o Medication practice standardization and Beacon protocol content
  o Oncology medications that have been approved under the 505(b)(2) pathway
• eCare related issues will be reviewed by the PPTC Chair and Vice-chair and, if deemed appropriate, may be subject to review and approval by PPTC
• The quorum is defined as 66% of the total committee
  o If the quorum was achieved for discussion of the voting item but absent for the voting, (thus losing the quorum for voting), the vote will be postponed to an email vote
If the quorum is lost, discussion of that item and subsequent voting will be suspended
To pass a motion, the quorum must be met, and approval is 66% by all attendees

1.2.2. Ambulatory Pharmacy Subcommittee
- This Sub-C will utilize expertise of multidisciplinary ambulatory pharmacy experts to provide stewardship of ambulatory medications across the system.
- The ambulatory Sub-C will provide recommendations to the PPTC for:
  - Forecasting
    - Identify key drugs expected to be approved by FDA and develop budget forecast
    - Develop strategies to manage drug costs (e.g., biosimilars, generic price increases)
  - Guideline development
    - Develop guidelines for key drugs identified (excluding oncology drugs)
  - Implementation
    - Co-ordinate implementation of required tools in eCare
  - Measurement
    - Assess prescriber adherence to guidelines and impact on healthcare costs
    - Assess patient adherence to medications
  - Best practice sharing
  - Drug safety
    - Serve as a forum to address emerging drug safety issues
- The quorum is defined as 66% of the total committee
  - If the quorum was achieved for discussion of the voting item but absent for the voting, (thus losing the quorum for voting), the vote will be postponed to an email vote
  - If the quorum is lost, discussion of that item and subsequent voting will be suspended
  - To pass a motion, the quorum must be met, and approval is 66% by all attendees

1.2.3. Employee Health Subcommittee
- This Sub-C will serve as the decision-making body for the Partners employee prescription drug benefit.
- Members will include a medical director and Partners Community Physicians Organization and ambulatory care pharmacists.
- This Sub-C will use the expertise of the PPTC, PPTC Sub-Cs, and/or clinicians across Partners to assist with formulary decision-making for the Partners Health Plan.

1.2.4. Neighborhood Health Plan P&T Committee
- This Committee will serve as the decision-making body for Neighborhood Health Plan.
- This Committee will use the expertise of the PPTC, PPTC Sub-Cs, and/or clinicians across Partners to assist with formulary decision-making or other medication-related issues for this Health Plan.

2. FUNCTION AND SCOPE

2.1. Formulary Management
- The Committee will establish a standardized cost-appropriate formulary for Partners HealthCare.
- Formulary products will be selected by an evidence-based process to be available for use at Partners HealthCare; some products may be restricted to certain services or have criteria for use.
- The formulary will be reviewed periodically to assess the continued efficacy, safety, and cost-effectiveness of medications.
2.1.1. Formulary Request Process

- Formulary modification requests will be submitted by local organization licensed independent practitioners or pharmacy departments to the PPTC (Figure 2) using the PPTC Formulary Request Form (Appendix 2). The Division Chief or Department Chair, local organization Chief Pharmacy Officer, and P&T chair must approve all requests. If an expedited formulary request is being made, the requestor will be required to check the reason(s) for such a request on the form. Approval from the Chief Medical Officer will be required if there is dissent among the aforementioned leadership group regarding the necessity of an expedited request.
- The Committee will focus on the review of medications; at the discretion of the Chair and Vice-Chair, the Committee may review nutraceuticals or dietary supplements.
- The decision to review surgically-related items may be undertaken in consultation with the Partners Procedural Committee which is managed by Partners Finance – Strategic Operations and Decision Support
- For medications on an existing formulary, the PPTC Chair and Vice-Chair, in consultation with the CDP, will determine if the request will be managed by the local organization P&T committee; this will typically be limited to medication(s) with a low potential for misuse or risk; or with minimal budget impact.
- The Committee will discuss formulary standardization with each formulary request
- The CDP, within one week of receipt of formulary request, will communicate to the formulary requestor, whether the formulary request will be handled by the PPTC or local P&T committee and within four weeks if the request for an expedited review is being considered (if applicable).

2.1.2. Formulary Reviews

Standard Formulary Review

- A full or abbreviated formulary review will be developed by the CDP in collaboration with a local organization using standardized templates.
  - Non-oncology medications: Evidence for on-label and off-label uses will be reviewed if available.
  - Oncology medications: Evidence for on-label use will be reviewed; off-label use will be managed according to local organization policy.
  - Biosimilars: Evidence for on-label and off-label uses will be reviewed if available.
- Full formulary reviews will be undertaken for medications primarily administered within the hospital or infusion clinics/areas, those with a potential for misuse, significant risk or budget impact.
- Abbreviated formulary reviews will be undertaken for medications, including medications in the 505(b)(2) pathway, with a low potential for misuse, risk or a minimal budget impact. This pathway avoids unnecessary duplication of studies already performed for the approval of a drug that has a new formulation for an already-approved drug.

Expedited Formulary Request

- The CDP will generate a preliminary review including but not limited to clinical information, insurance coverage, and a budget impact analysis plus recommendations regarding the necessity of an expedited review.
- The PPTC Chair and Vice-Chair will:
  - Review the formulary request, CDP’s preliminary review, and consult with subject matter experts to evaluate the expedited formulary request based on medical necessity, clinical efficacy, and economics.
Render and communicate a decision to the CDP within four weeks of receiving the expedited formulary request. Decision options include:

- Defer request pending completion of standard formulary review process
- Deny request and formulary review
- Grant provisional use pending completion of the standard formulary review process.
  - Provisional use criteria will be developed by the CDP in collaboration with subject matter experts and the PPTC Chair and Vice-Chair; these are subject to change following the completion of the standard formulary review.
  - Once provisional use criteria are approved, the medication may be used at the requesting organization(s).
  - The formulary request will cycle into the standard formulary review process.

The CDP will notify the requestor of the PPTC Chair and Vice-Chair’s decision.

**Feasibility Study Formulary Request**

- The requesting organization may submit a formulary request form requesting to assess the feasibility of adding an agent to formulary which outlines: the specific patient population with the specific disease state in which the intended agent will be used, number of patients, duration of study, cost of intervention, detailed plan
- Agents that are non-formulary or expansion of use of existing formulary agents are eligible for consideration of a feasibility study
- Feasibility studies are not eligible for expedited review
- To be considered for a feasibility study, the agent being requested will be limited to the specific number of patients intended for use
- The PPTC Chair and Vice-Chair will review the feasibility study proposal and determine whether to either approve or deny the feasibility study request based on safety and cost concerns. The PPTC Chair and Vice-Chair will notify local institution P&T Chairs and CPOs via email about a feasibility study request to determine if other sites have had similar inquiries about a particular medication. The PPTC Chair and Vice-Chair will decide if the feasibility study will be presented to the full PPTC. This decision will be partly based on network-wide interest.
- If decided that the feasibility study will be presented to the full PPTC, then the feasibility study is subject to full review by the appropriate Sub-C
- The CDP will notify the requestor of the PPTC decision
- Once results have been presented to the PPTC, the request, if for a non-formulary agent, may then be eligible to be cycled into the standard formulary review process
- The requesting organization must present their findings to the appropriate Sub-C and the PPTC in the specified timeframe outlined in their protocol

**2.1.3. Sub-C Review**

- The formulary review and draft recommendations will be submitted by the CDP to Sub-C(s).
- The Sub-C(s) will convene and provide recommendations to the PPTC; members who are unable to attend the meeting may provide recommendations via email. Recommendations from the Sub-Cs will be summarized in meeting minutes and will be made accessible to the PPTC.
- Relevant Sub-C recommendations will be submitted to the PPTC for final review.
**Figure 2: Formulary Request Process**

Formulary request

PPTC

New drug to Partners or drug on formulary with new efficacy, safety, or economic data

Drug on formulary at least at one organization

Assess efficacy, purchases, safety, resource utilization

Grandfathering process
(i.e., local P&T committee undertakes formulary review using pre-existing materials from other organizations if available)

Standard formulary review process

Expedited formulary request process

Formulary review & draft recommendations (CDP +/- local organization)

Sub-C(s)
1. Specialty

Sub-C(s) recommendation(s)

PPTC decision

Local P&T committees

Formulary requestor

eCare*

Implementation

Appeals (optional)

Implementation

Responsibilities: Box Fill: Blue=Local organization; Green=CDP/PPTC process; Pink= eCare
Diamond pattern= CDP & local organization; Striped pattern: CDP & PPTC Chair and Vice-Chair

^The CDP may initiate formulary reviews based on forecasted budget impact or utilization. *Oncology decisions will also be communicated to the Oncology Service Line Committee.
2.1.4. PPTC Presentation

- The formulary request, formulary review and draft recommendations, and summary of Sub-C(s) recommendations will be presented to the PPTC for formulary decision making.
- The CDP will invite the:
  - Formulary requestor to present the formulary request in person or designate an alternate or present at the next available meeting if the formulary requestor cannot present at the scheduled meeting. Where there are multiple requestors, the requestors will be asked to nominate one individual to represent them; exceptions may be made as needed.
  - If the formulary requestor is a voting member of the PPTC, he/she must recuse and/or abstain him/herself during the voting of that item
  - Clinical expert(s) at organization(s) where the medication is already on formulary to share their experience with the medication (if applicable). Where there are multiple experts, they will be asked to nominate one individual to represent them; exceptions may be made as needed.
- The CDP will present the materials on behalf of the, local organization, Sub-Cs, or clinical experts if they are unable to attend the meeting.
- The PPTC will vote on the formulary request and/or formulary review and recommendations.

2.1.5. Formulary Appeals

- The formulary requestor may appeal a PPTC formulary decision using the PPTC appeals form (Appendix 3). Approval and signature from the Division Chief or Department Chair, local organization Chief Pharmacy Officer, P&T Chair, and Chief Medical Officer are required for appeal submission.
- The appeals process is applicable if significant new evidence (e.g. clinical trial data, guidelines, safety data etc.) is provided that would alter clinical practice or if the requestor deems the PPTC processes/decision to be unjust figure 3).
- Appeals with new evidence will be reviewed by the PPTC Chair and Vice-Chair (see table 1; page 9). Sufficient evidence for an appeal includes submission of treatment guideline(s), meta-analyses, randomized controlled trial(s), or adequately designed observational studies with controls for relevant confounding factors.
- Appeals deemed unjust by the formulary requestor will be reviewed by Partners Clinical Leadership [Chief Clinical Officer (CCO), Chief Quality and Safety Officer (CQSO), and Chief Medical Officer’s (CMO) Council Chair] and will be escalated to the full CMO Council for a final determination (see table 1; page 9). Only CMOs from Partners member-institutions will be eligible to vote on PPTC appeals.
Table 1: Formulary Appeals Process

<table>
<thead>
<tr>
<th>CDP Action</th>
<th>PPTC Chair and Vice-Chair Action</th>
<th>Partners Clinical Leadership Action</th>
<th>CMO Council Action</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Appeal Type: PPTC Decision Deemed Unjust</strong></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>• Review the appeals form and meeting minutes</td>
<td>• Review the appeals form, meeting minutes, supporting literature, and other applicable documents</td>
<td>• Review the appeals form, meeting minutes, supporting literature, and other applicable documents</td>
<td></td>
</tr>
<tr>
<td>• Consult with formulary requestor, as needed</td>
<td>• Render and communicate a determination to the PPTC</td>
<td>• Render and communicate a determination to the PPTC</td>
<td></td>
</tr>
<tr>
<td>• Provide appeals form, meeting minutes, and other documentation as appropriate, to Partners Clinical Leadership and CMO Council</td>
<td>• Participate in CMO Council meeting(s) if applicable</td>
<td></td>
<td></td>
</tr>
<tr>
<td>• Participate in CMO Council meeting(s) if applicable</td>
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</tbody>
</table>

**Determinations include**
- Sufficient evidence from PPTC; escalate to CMO Council
- Insufficient evidence; request additional evidence from PPTC

| **Appeal Type: New Evidence** | | | |
| • Provide appeals form and meeting minutes to PPTC Chair and Vice-Chair | • Review the appeals form, meeting minutes, CDP’s preliminary review, supporting literature, and other applicable documents | Not applicable | Not applicable |
| • Generate a preliminary review including but not limited to clinical information, insurance coverage, and a budget impact analysis plus recommendations regarding the necessity of an appeal | • Consult with subject matter experts, and/or formulary requestor as needed | | |
| | • Render and communicate a determination to the CDP | | |

**Determinations include**
- Sufficient evidence: Standard formulary review
- Insufficient evidence: Deny appeal

**Notification of Determinations**
- Appeal with new evidence:
  - The CDP will notify the requestor, PPTC members, local organization’s Chief Pharmacy Officer, P&T Chairs and secretaries
- Appeal Where PPTC Decision Deemed Unjust:
  - The CMO council’s designee will notify the formulary requestor
  - The CDP will notify PPTC members, local organization’s Chief Pharmacy Officer, P&T Chairs and secretaries
Appeal submitted due to new evidence or PPTC decision deemed unjust

If new evidence is provided

Preliminary assessment of efficacy, safety, budget impact and necessity of appeal

If PPTC decision deemed unjust

PPTC Chair & Vice-Chair determination

Subject matter experts and/or formulary requestor consulted (optional)

Review appeals form, meeting minutes, and supporting documents

Request additional documents

Partners Clinical Leadership determination

CMO Council determination

PPTC process transgression; follow standard formulary review

PPTC process validated; uphold PPTC decision

Notification to: Formulary requestor, Local P&T and PPTC

Responsibilities: Flowchart Shape Fill:
Blue=Local organization; Green=CDP; Peach=Chief Clinical Officer, Chief Quality & Safety Officer, and Chief Medical Officer Council Chair; Purple: Chief Medical Officer Council; Yellow: PPTC Chair and Vice-Chair
Diamond pattern=CDP & local organization; Striped pattern=CDP & PPTC Chair and Vice-Chair

2.2. Drug Use Policy

Created: Oct 2013
Revised Jan, Mar, May, Aug, Dec 2014, Mar 2016, Sept 2017
To be revised: Dec 2018
Center for Drug Policy
Confidential
The Committee will review and approve policies related to the use, administration and monitoring of pharmaceuticals across the System.

2.3. Monitoring

- The CDP will systematically monitor and evaluate the use of drugs added to the formulary using the following steps:
  - Review purchase history on a periodic basis (i.e. quarterly, annually) to assess trends in expenditures via a dashboard
    - The dashboard will review Partners decisions and drug spend as well as information regarding reimbursement, utilization and benchmarking
  - Conduct an annual benchmarking evaluation of drugs on formulary, comparing use against similar hospitals nationwide using the Vizient tool and/or other tools, as appropriate.
  - A medication use evaluation (MUE) to examine the degree to which prescribers are adhering to the recommendations in the formulary guideline will be considered for drugs that meet at least two of the following conditions:
    - Drugs with high expenditures (>500,000/year)
    - Consistently rising expenditures
    - High utilization (i.e. use greater than projection at time of formulary review and/or greater than use at other similar institutions)
  - Additional MUEs will be conducted per recommendations from the PPTC based on potential for inappropriate use or adverse events of concern.
  - Based on the evaluation of the data and outcomes the Committee will provide recommendations including but not limited to formulary modifications to improve the quality and cost-effectiveness of drug therapy.
  - Safety and incident reports as provided by local institutions.

2.4. eCare Decisions

- The eCare team will receive requests from the Willow team and will vet necessary materials through eCare subject matter experts. Once consensus has been reached among subject matter experts, the material will be presented to the PPTC for approval.
- The issue needs to be clearly outlined, along with the decision timeframe as well as the voting question(s) on which the PPTC will be voting.
- The Committee will provide recommendations to the eCare team regarding formulary modifications, standardization and other items deemed appropriate by the Committee.
- The Committee will serve as the final arbitrator for items that cannot be resolved (i.e. the Pharmacy Control Board will be the main entity responsible for standardizing medication administration with escalation to Clinical Collaborative teams if needed).
  - The issue needs to be clearly outlined, as well as the voting question(s) on which the PPTC will be voting; additional reviews may be requested/generated prior to such a vote.

2.5. Ad Hoc Items

- Other drug-related ad hoc items deemed relevant by the Committee Chair will also be reviewed.

3. DECISION MAKING PROCESSES

3.1. Attendance and Voting Requirements
• Members are encouraged to attend all meetings and in the event they cannot attend, to send an alternate as outlined in Section 1.1 to meet the quorum requirements.
• The quorum is defined as 66% (23 out of 35 members) of the total committee with at least 66% of the BWH and MGH members in attendance (8 out of 12 members).
  o If the quorum was achieved for discussion of the voting item but absent for the voting, (thus losing the quorum for voting), the vote will be postponed to an email vote.
  o If the quorum is lost, discussion of that item and subsequent voting will be suspended.
• To pass a motion, all of the following are required of those present for a vote:
  o 66% approval by all attendees
  o 50% approval by BWH and MGH attendees
  o 50% approval by attendees from all other entities
• Voting results will be calculated based on the total number of voting responses (e.g., yes, no, abstain) for the item.
• When an alternate delegate attends a meeting in-lieu of a Committee member, this individual will be eligible to vote on Committee decisions.

3.2. Facilitation of Decision Making
• The Committee Chair will facilitate the meeting agenda and discussion of items.
• The Committee Chair will invite a motion to be made for action. The motion will be seconded by a voting member of the Committee. The Committee Chair will request any COIs be disclosed following the motion and prior to the vote being cast. Any member with a COI will abstain from voting for the particular item; however, the member does not have to recuse him/herself from the item discussion.
• Voting items may include but are not limited to:
  o Formulary status
    ▪ Add drug to formulary without restrictions
    ▪ Add drug to formulary with restrictions
    ▪ Do not add drug to formulary; deny the formulary request
      ❖ Where a medication is already on formulary at an organization, an additional vote will be undertaken to remove the drug from the local formulary or grandfather in use. In cases of grandfathered use the organization will implement any Partners criteria for use (see table 2 section 4.2)
    ▪ Remove from formulary
    ▪ Postpone voting until further data are available
  o Formulary review/criteria for use/other medication-related issues: approve, reject, or modify the criteria for use
• All votes, including voting via email, will be recorded in the PPTC meeting minutes.

4. COMMUNICATIONS AND IMPLEMENTATION OF DECISIONS

4.1. Documentation and Notification of Decisions
• The CDP will prepare and distribute the draft meeting minutes no later than one week prior to next scheduled meeting.
• The CDP will notify requestor(s) of the formulary decision no later than two weeks after distribution of the minutes.
  o If the formulary request is denied, the rationale for Committees’ decision and information regarding the appeals process will be provided to the requestor.
In the event that voting is postponed, the requestor will be notified of the postponement and expected timeframe for notification of the final decision.

- Previous meeting minutes will be reviewed as an order of business at each meeting. Any corrections will be reflected in the current meeting minutes and in the minutes under review.
- The CDP will distribute the finalized minutes no later than one week after the meeting.
- If a drug is approved for formulary addition, the approved formulary review will be housed on the Partners Handbook CDP website.

4.2. Implementation of Decisions

- The local organization P&T committee:
  - Will be responsible for implementation of PPTC decisions as recorded in the PPTC meeting minutes and, applicable to that organization (e.g., patient population, services provided); the method of implementation is to be determined by the local organization.
  - May elect to implement stricter criteria for use than a PPTC-approved decision, including not adding a drug to formulary or removing a drug from formulary, if that local organization deems this to be appropriate.
  - May grandfather formulary status if a drug has already been on formulary at their organization and the PPTC votes not to add the drug to formulary but approves grandfathering. See the table below for guidance.
  - Will remove drugs from the local formulary if the PPTC votes not to add an existing drug to the formulary and rejects grandfathered use (Table 2)
  - Will not be able to override decisions made at the PPTC
  - Is responsible for communication of applicable PPTC decisions as recorded in the PPTC meeting minutes, (modified as appropriate to their organization) to their Medical, Nursing and Pharmacy departments and any other staff.

Table 2: Implementation of PPTC formulary decisions

<table>
<thead>
<tr>
<th>Formulary Status</th>
<th>Voting Item</th>
<th>PPTC Decision</th>
<th>Local Organization Action</th>
</tr>
</thead>
<tbody>
<tr>
<td>New drug to Partners</td>
<td>Formulary status</td>
<td>Add drug to formulary</td>
<td>• Add drug to formulary or • Do not add to formulary</td>
</tr>
<tr>
<td></td>
<td></td>
<td>Do not add drug to formulary</td>
<td>• Do not add to formulary</td>
</tr>
<tr>
<td></td>
<td>Formulary review and criteria for use</td>
<td>Approve</td>
<td>• Present formulary review at P&amp;T meeting if use is applicable to organization population • Implement criteria for use or • Implement stricter criteria for use</td>
</tr>
<tr>
<td>Drug on at least one local formulary with new efficacy, safety or economic data</td>
<td>Formulary status</td>
<td>Add drug to formulary</td>
<td>• No change required</td>
</tr>
<tr>
<td></td>
<td></td>
<td>On local formulary</td>
<td>• Add to formulary or • Do not add to formulary</td>
</tr>
<tr>
<td></td>
<td></td>
<td>Not on local formulary</td>
<td>• Remove from formulary • Do not add to formulary</td>
</tr>
</tbody>
</table>
### Formulary Status

<table>
<thead>
<tr>
<th>Voting Item</th>
<th>PPTC Decision</th>
<th>Local Organization Action</th>
</tr>
</thead>
<tbody>
<tr>
<td>Do not add to formulary; approve grandfathered use</td>
<td>• May grandfather formulary status <strong>or</strong> • Remove from formulary</td>
<td></td>
</tr>
<tr>
<td>Remove drug from formulary</td>
<td>• Remove from formulary</td>
<td>• No action required</td>
</tr>
<tr>
<td>Formulary review and criteria for use</td>
<td>Approve</td>
<td>• Present formulary review at P&amp;T meeting • Implement criteria for use <strong>or</strong> • Implement stricter criteria for use</td>
</tr>
</tbody>
</table>

- eCare will be responsible for Epic implementation of formulary or drug-related decisions.

5. **MEETING SCHEDULE AND LOCATION**
   - The Committee will meet monthly (or other schedule, as deemed appropriate by the Committee) at a Partners location; a webinar and teleconference will also be available.
   - Meeting materials (e.g. agendas, slides, and meeting minutes) will be distributed prior to meetings.
   - Executive sessions will be held as needed when Partners confidential information is discussed; non-Partners organizations (e.g. DFCI, MEEI) will be asked to recuse themselves from session attendance.

6. **DISCLOSURE OF POTENTIAL CONFLICTS OF INTEREST**
   - All members of the Committee and Sub-Cs will be required to disclose potential COI.
   - The CDP will utilize information reported to the Partners Compliance and Business Integrity Office, which oversees a Partners-wide COI disclosure process. Individuals who do not have a COI disclosure on file with this Office will be directed to the appropriate person(s) by the CDP to file such a COI disclosure.
   - Individuals who do not report to the Partners Compliance and Business Integrity Office (e.g. DFCI, MEEI) will be contacted via email by the CDP to file a COI disclosure.
   - Annually, the CDP will submit a Request for Individual Partners Conflict of Interest Disclosure Form to the Partners Compliance and Business Integrity Office, overseen and signed by the Director of the CDP.
   - The CDP will submit a Request for Individual Partners Conflict of Interest Disclosure Form to the Partners Compliance and Business Integrity Office for each ad hoc specialty sub-C.
   - The COI disclosure for the Committee and Sub-C members should be revised if a new relationship comes into existence; this information should be conveyed at or by the time of the following month’s meeting to the CDP.
   - See section 3.2 for COI implications on Committee voting.
Appendix 1: Representation on the PPTC and Subcommittees by organization and specialty

Table 1: PPTC

<table>
<thead>
<tr>
<th>Organization</th>
<th>Chief Pharmacy Officer</th>
<th>P&amp;T Chair</th>
<th>Chief Medical Officer</th>
<th>Attending Physician</th>
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Table 2: Oncology Subcommittee

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<tr>
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*Vice-chair is Vice-President of Pharmacy Services; **Chair is MGH physician

Table 3: Ambulatory Pharmacy Subcommittee

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<th>Entity</th>
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<tr>
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<td>MD or RPh</td>
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<tr>
<td>MGH</td>
<td>RPh</td>
<td>Hospital ambulatory pharmacy</td>
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<td>PHS – specialty pharmacy</td>
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*Chair is BWPO physician; **Vice-chair is MGPO pharmacist, ^eCare is a non-voting member

Appendix 2: Partners Pharmacy and Therapeutics Committee Formulary Request Form

Created: Oct 2013
Revised Jan, Mar, May, Aug, Dec 2014, Mar 2016, Sept 2017
To be revised: Dec 2018
Center for Drug Policy Confidential
Partners Pharmacy and Therapeutics Committee Formulary Request Form

This form is used to request modifications to the Partners formulary. All portions of this form must be completed or it will be returned. This Word document can be typed on directly. Please do not alter the form. To check a box, double click on the box and change the default value to checked. When typing directly on the document you can file/save as/save to your own drive. Once complete, please email to PPTC@partners.org

I. Formulary Modification Requested □ Addition □ Deletion* □ Restriction*

*If you are requesting a deletion or restriction, please provide reason(s) for deletion or conditions for restriction: ____________________________________________

Expedited Formulary Request: □ Yes □ No If yes, select one or more of the following:

- Termination of clinical trial when the drug gains FDA approval
- No available formulary alternative
- FDA designated breakthrough therapies§
- Not a chronic oral outpatient therapy
- Significant cost savings associated with inclusion of the drug on formulary

Please note that expedited formulary requests are reviewed by the PPTC Chair, Vice Chair, and appropriate subject matter experts to determine if provisional use is necessary prior to the completion of the standard formulary review. A decision will be rendered within four weeks of receiving the expedited request. An expedited formulary request does not alter the timeframe required to complete the standard formulary review.

II. Drug Information:

- Generic name: _____________________________  Trade name(s): ________________________________
- Manufacturer(s): __________________________________________________________________________
- Mechanism of action: ______________________________________________________________________
- Usual dose, route of administration, frequency, and duration of therapy:_________________________
- Will the drug be used for an FDA approved indication? □ Yes □ No
- If this is an off-label formulary request, please provide the intended use(s): ______________________
- Estimated annual number of patients: ________________________________________________________

Number of patients who will be transitioned from clinical trial (if applicable):_____________________

Estimated date of transition off clinical trial (if applicable):______________________________________

   Inpatient: □ Yes □ No   Outpatient: □ Yes □ No   Both: □ Yes □ No
   Adult: □ Yes □ No       Pediatric: □ Yes □ No       Both: □ Yes □ No

- Comparable drug(s) on formulary: ____________________________________________________________
- Situations in which this drug is superior to those on formulary (Attach additional sheets if necessary):

Created: Oct 2013
Revised Jan, Mar, May, Aug, Dec 2014, Mar 2016, Sept 2017
To be revised: Dec 2018
Center for Drug Policy Confidential
• Which drug(s) listed above could be deleted from the formulary if this agent were added?

• Special cautions and restrictions of use:

• Pertinent literature references (Please attach):

• Suggested criteria for use (Please attach additional sheets if necessary):
  1. Inclusion criteria:

  2. Monitoring parameters (Including adverse drug reactions/interactions that may occur and preventive and/or responsive management for each):

  3. Outcome measures (Markers to determine drug efficacy):

III. Miscellaneous Information:
• Have you been an investigator in any research study involving this drug? □ Yes □ No
• In the last two years, have you served as an advisor, received honoraria and/or research funding from the current or previous company manufacturing or promoting this product? □ Yes □ No
• Do you have equity (outside of a mutual fund) in the manufacturer of this drug? □ Yes □ No
• Do you have any issues that would be considered a Conflict of Interest regarding this drug? □ Yes □ No
• If you answered “yes” to any of these questions, please provide further details of your relationship:

  Have you completed the Individual Partners Conflict of Interest Disclosure Form? □ Yes □ No

Organization: □ BWH □ BWFH □ CDH □ DFCI □ McL □ MEEI □ MGH □ MVH □ NCH □ NSMC □ NWH □ SPH

Requested by: __________________Date: ____________ Dept./Division: ______________________________

□ Approved by Division Chief or Department Chair:
□ Approved by Pediatric Division Chief or Department Chair if pediatric use requested:
□ Approved by Local Organization P&T Chair:
□ Approved by Local Organization Chief Pharmacy Officer:
Appendix 3: Partners Pharmacy and Therapeutics Committee Formulary Appeals Form

The formulary requestor may use this form to appeal a formulary decision rendered at the PPTC. All portions of this form must be completed or it will be returned. This Word document can be typed on directly. Please do not alter the form. To check a box, double click on the box and change the default value to checked. When typing directly on the document you can file/save as/save to your own drive. Once complete, please email to PPTC@partners.org

I. Drug Information:

• Generic name: _____________________________  Trade name(s): ________________________________

If this is an off-label formulary request please provide the intended use(s): __________________________

II. Please provide rationale for formulary appeal

____________________________________________________________________________________________

____________________________________________________________________________________________

III. New Evidence (if applicable)

• Pertinent literature references (Please attach):____________________________________________________

• Suggested criteria for use (Please attach additional sheets if necessary):
  1. Inclusion criteria: _________________________________________________________________________
  2. Outcome measures (Markers to determine drug efficacy): _________________________________________________________________________

Institution: □ BWH  □ BWFH  □ CDH  □ DFCI  □ McL  □ MEEI  □ MGH  □ MVH  □ NCH

□ NSMC  □ NWH  □ SPH

Requested by: _____________________________________  Date: ____________________________

Printed name: _________________________________  Dept./Division: _____________________________

Division Chief or Department Chair: Name: ___________________ Signature__________________________

Local Organization P&T Chair: Name: ___________________ Signature_______________________________

Local Organization Chief Pharmacy Officer: Name: ___________________ Signature____________________

IV. Chief Medical Officer: Please provide rationale for support of formulary appeal:________________________

____________________________________________________________________________________________

Name:________________________ Signature_________________________________________________________