P&T Committee Drug Prioritization Criteria: A Tool Developed by a Saudi Health Care System

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ABSTRACT

Introduction: The workflow of a P&T committee can become overwhelming and may be affected by many internal and external factors. Organization, standardization, and an enhanced systematic approach for drug evaluations are necessary to ensure that all requested drugs receive an equal and unbiased evaluation and consideration for addition based on the institution's objectives, priorities, and budget. Our aim was to create a scoring tool that would assist in systematically prioritizing drugs being requested for formulary addition and to eliminate cumbersome evaluations for drugs that clearly do not offer any additional advantage.

Methods: A working group consisting of P&T committee members met with the task of creating initial screening criteria for prioritizing drugs requested for formulary addition. Members conducted independent literature searches and focused meetings to develop a scoring tool that would be piloted on drugs being requested for addition.

Results: We developed a scoring tool to prioritize drugs requested for formulary addition. The tool assigns a score for each drug that allows it to be classified into one of three categories: 1) for expedited review, 2) for routine review, or 3) for rejection without the need for a full evaluation.

Conclusions: We believe that this scoring tool will assist in prioritizing drugs requested for formulary addition while allowing for full consideration of the most important decision-making factors. In an era of expected U.S. Food and Drug Administration deregulation and economic constraints, P&T committees must create tools that ease their workflow and organize their priorities.

Keywords: pharmacy and therapeutics committee, P&T, prioritization criteria, P&T decision-making, drug expenditure

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INTRODUCTION

The Ministry of National Guard Health Affairs (MNGHA) is a large tertiary health care system with a level 1 trauma center that was established in 1983 to provide state-of-the-art medical care to the National Guard's soldiers and their dependents in three regions of Saudi Arabia. MNGHA is a leader in health care services in the Middle East,[1] with facilities in the Central, Eastern, and Western regions of Saudi Arabia. In Riyadh alone, King Abdulaziz Medical City has a capacity of 1,500 beds at its main hospital and 600 beds at its King Abdullah Specialized Children Hospital. All MNGHA health care facilities are accredited by the Joint Commission International[2] and strive for excellence and the global best practice standards, including an enhanced formulary management system.

At our institution the formulary is unified among regions and steered by one centralized committee, known as the Corporate Pharmacy and Therapeutics Committee (CP&T). The committee is responsible for selecting formulary drugs based on the best available evidence on safety, efficacy, and cost and overseeing the appropriate use of medications throughout the institution. The committee has six main subcommittees that report to the main CP&T committee, where final decisions are discussed and motions are made.

Historically, each region had its own regional P&T committee that would conduct a scientific drug evaluation for any drug that was requested for formulary addition from prescribers in the region. The regional recommendations would then be submitted to the CP&T committee for a final decision. At that time, each region did its scientific evaluation differently and methods of evaluating drugs were inconsistent across the regions, which led to considerable debate during the final discussion at the CP&T committee. Ultimately, many formulary decisions were deferred; therefore, a call for a standardized, evidence-based, unified method was made and the process of drug evaluation was revised in 2013. Subsequently, evaluations for drugs requested from all regions were centrally processed through three subcommittees branching from the CP&T committee, which included members from all regions with diverse representation from physicians, pharmacists, logistics and supply, pharmacoeconomics, and information technology.

The six subcommittees reporting to the CP&T committee are:

- Corporate Drug Evaluation Subcommittee (CDES), which evaluates all new drug requests other than antimicrobials or oncology/hematology drugs
- Corporate Antimicrobial Subcommittee (CAS), which evaluates new antimicrobial drug requests

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- Corporate Oncology Pharmaceutical Subcommittee (COPS), which evaluates new oncology/hematology drug requests
- Three regional committees, which mainly focus on the evaluation of new dosage forms, local therapeutic policies, standards of practice, monitoring, and addressing logistics issues with supply and consumption of drugs.

RATIONALE FOR PRIORITIZATION CRITERIA

The workflow of a P&T committee can become overwhelming and may be affected by many internal and external factors.[3–5] Organization, standardization, and an enhanced systematic approach for drug evaluations are necessary to ensure that all requested drugs receive an equal and unbiased evaluation and consideration for addition based on the institution's objectives, priorities, and budget.[3]

Upon implementation of our standardized, evidence-based drug evaluation process and use of the Grading Recommendations Assessment, Development, and Evaluation (GRADE) system for assessing quality of evidence, the quality and transparency of drug evaluations submitted for P&T discussion improved significantly. However, the drug review process became cumbersome. Each drug evaluation consumed a substantial amount of time for evaluating the quality of evidence and providing a full pharmacoeconomic evaluation with no prioritization other than a first-come, first-evaluated basis. This increased the number of drugs awaiting evaluation.

A report by the World Health Organization indicated that in 2010 the total pharmaceutical expenditure in Saudi Arabia was 13.5 billion Saudi Arabian riyal (SAR) ($3.5 billion U.S. dollars [USD]),[7] and a more recent report estimated that the figure reached approximately 32.5 billion SAR ($8.46 billion USD) in 2015 with a 10% annual growth rate.[8] This project is part of a series of initiatives taken by our committee to judiciously manage our pharmaceutical expenditure and rationalize our drug formulary selection.[9]

With Saudi Arabia's new economic constraints, prompted by its new vision for year 2030,[6] it was imperative to take the initiative to implement additional measures to strategically consider drugs for formulary addition with an optimum utilization of resources. Therefore, our project aimed to develop criteria for assessing drugs for formulary addition to avoid delay in evaluating important and practice-changing drugs and to improve the efficiency of the P&T committee's workflow. To our knowledge, there is a paucity of data on guiding prioritization of drugs for formulary addition.

METHODS

The CDES administrative members (chair, co-chair, and coordinators from the regional subcommittees), together with the pharmacoeconomic expert, formulated a working group that aimed to create initial prioritization criteria for classifying drugs for formulary addition into one of the following categories:

- Expedited review: Evaluation is done in one to two months and bypasses other items in the queue.
- Routine review: Evaluation is done in two to four months, depending on other items in the queue.
- Rejected: Full evaluation will not be done.

The initial step was to conduct an independent literature search to identify any previous publications or experiences related to the screening and prioritization of drugs requested for formulary addition. None of the members was able to identify related publications of prioritizing criteria. Furthermore, the majority of the literature addressed the overall decision-making process of P&T committees.[10–12] However, our target was to create a tool that could be used as an initial step in filtering requests and prioritizing drugs in a logical, objective order to determine if a full evaluation and discussion were warranted.

Next, we held focused group meetings. The working group met to develop a scoring tool in a simple, user-friendly format that considers all of the main factors that should be taken into consideration when making a formulary decision. As a starting point, the pharmacoeconomic expert suggested that we consider the points used in health technology assessment for setting priorities at organizations such as the National Institute for Health and Care Excellence in the United Kingdom and the Canadian Agency for Drugs and Technologies in Health.[13,14] Although these systems are not intended for P&T committee decision-making, both have criteria for drugs to be prioritized for evaluation. Because their objectives and goals differ from our institution's, we tailored our scoring tool to reflect factors that we agreed were crucial in our decisions based on literature and institutional experience.[3,10–12] For example, the cost impact was estimated using the pharmacoeconomic evaluations of drugs that were added to the MNGHA formulary over the past year to create five categories, reflecting the cost impact a drug might have on our institution.

To validate the process, we piloted the tool on a number of drugs previously evaluated by our committee, as well as on randomly selected drugs that were in the queue for future evaluation (not all drugs in the queue were included). All drugs were reviewed and scored by two clinical pharmacists independently to test for variations. Several revisions were made based on discussion and disputes, and finally the group presented the prioritization criteria and the new scoring tool to a larger group of experts (the CP&T committee members) for their feedback.

RESULTS

Focused Meetings Outcome

After several meetings, the working group agreed on the main factors that are to be considered in the prioritization process. These factors were:

- ***Body of evidence:*** The type of study design of published scientific evidence related to the efficacy/safety of the drug, such as randomized controlled trials (RCTs) or meta-analyses. We focused on RCTs as they are the required evidence for regulatory approval of drugs.
- ***Population affected:*** The size of the population that would benefit from the treatment, which provides insight on the prevalence and incidence of the disease to quantify the overall number of patients who will gain benefit from the drug.
- ***Disease severity:*** Morbidity and mortality of the disease, which was divided into three levels: significant morbidity or mortality, moderate morbidity, or minimal morbidity.

- ***Therapeutic benefit:*** Assessing the magnitude of the effect, which was divided into three levels: significant, moderate, or negligible potential additional therapeutic benefit versus the drug's active comparator if any or placebo.
- ***Safety:*** Assessing the magnitude of expected adverse events for drugs using various measures of association as reported in literature (e.g., the relative risks versus potential comparators).
- ***Cost impact:*** Estimation of the direct impact that addition of a drug will have on the budget based on the size of the population expected to benefit from treatment with the drug and the price quote for our institution.
- ***Patient preference:*** The patient's perspective is taken into account with an assessment of the preferences that are considered important for improving adherence and quality of life (i.e., injectable versus oral medications, less frequency of administration, better safety and tolerability).
- ***Availability of therapeutic alternatives on the formulary:*** Whether the formulary already has therapeutic options to treat the same disease/condition or if the drug has an innovative mechanism of action clearly superior to the formulary alternative.

Each of the factors mentioned above was given a relative weight in percentage out of 100%, which would reflect its importance in guiding the decision. The scoring tool was designed to be user friendly. See Table 1 for the scoring tool developed for prioritizing drugs being requested for formulary addition and Table 2 for an example using dexlansoprazole (Dexilant, Takeda Pharmaceutical Company Ltd.).

Piloting Results

Five clinical pharmacists involved in P&T committee activities took part in the piloting phase. Tables 3 and 4 present the scores of drugs piloted and reviewed by two independent clinical pharmacists.

Of 10 drugs in the queue for evaluation, four scored less than 30%, which would place them in the rejected category and disqualify them for a full evaluation. Five of the drugs scored between 30% and 70%, deeming them eligible for a routine review. None of the drugs selected for the piloting phase scored above 70%, which would render them eligible for expedited review and evaluation. Out of all drugs piloted, a discrepancy between scoring was seen only with one drug, which led to its classification by one reviewer for rejection and by the other reviewer for routine review (see Table 3, pirfenidone [Esbriet, Genentech]). After assessing both reviewers' method of scoring along with their comments, one explanation for the disagreement was that one reviewer, when scoring for the factors "therapeutic benefit" and "safety," used a nonformulary drug as the comparator, which led to a lower score compared with the other reviewer, who used formulary alternatives for comparison. It was then emphasized that, when scoring is done, the formulary therapeutic alternative should be used as a comparator.

The three drugs selected for piloting that had been evaluated previously and with a decision already made by the CP&T committee produced similar results when scored using the tool. Bisoprolol and duloxetine scored less than 30% by two reviewers and had been rejected in the previous year by our CP&T committee. Apixaban (Eliquis, Bristol-Myers Squibb) scored 55% and 70%, making it suitable for an expedited review; this was consistent with the decision of our committee to approve apixaban for formulary addition.

On average, the time required for scoring the drugs using the tool was reported by the reviewers to be around a couple of hours. This is an essential factor because our committee members have full-time clinical positions in addition to academic affiliations.

DISCUSSION

In an era of expected U.S. Food and Drug Administration deregulation meant to push forward innovation, more new drugs are expected to reach the market.[15] As a result, it is now more crucial than ever that P&T committees establish structures to organize their responsibilities and develop tools to ease their workflow and consolidate their priorities.

The aim of developing this tool was to avoid the cumbersome effort of a complete drug evaluation if the drug does not pass through preset criteria in the initial screening process. Thus, the process maximizes the organization's resources while allowing access to breakthrough treatments that require priority review in an expedited manner and, therefore, improving patient care.

We developed an institutional scoring tool that can be used easily for screening drugs requested for formulary addition. It will allow each drug to be given appropriate priority among the other drugs in the queue.

The tool takes into consideration eight factors: first, the body of evidence, which gives consideration to the hierarchy of evidence; second, the size of the affected population, which reflects the institution's population priority and burden of the disease; third, the disease severity and its associated morbidity and mortality (i.e., drugs to treat hepatitis C should have priority over drugs used to treat acne vulgaris); fourth, the therapeutic benefit based on the requested indication, weighing the magnitude of benefit and its important impact on clinical patient-centered outcomes; fifth, the safety of the drug and whether it has less potential to cause serious harm when compared to a therapeutic alternative; sixth, the cost impact, one of the highest-weight factors in the tool in line with the organization's directive to judiciously cut pharmaceutical expenditures; and seventh, patient preference, which we recognized as an important link in evidence-based practice and excellent quality of care. Seeking balance for drugs that would score low on body of evidence due to unavailability of comparative evidence with other drugs but are considered innovative based on mechanism of action, we added "therapeutic alternative" as the eighth factor. This allows these drugs to gain a higher score, taking into account the availability of alternatives already on the formulary.

We chose rejection for drugs that scored less than 30% based on our committee's goal of turning down drugs that clearly offer no advantage on all factors in the scoring tool, and we awarded expedited review for drugs that scored above 70% (a score that would be difficult to reach) to prioritize drugs that would definitely have a unique combination of advantages.

Table 1 Scoring Tool Developed for Drug Prioritization Review

Criterion	Description	Weight (%)	Weight	Range of Weighted Scores	
Body of evidence	Published scientific literature that provides evidence of the drug's benefits	10%	20	0 to 20	
Population	Size of the population that would benefit from treatment with the drug	10%	20	0 to 20	
Disease severity	Morbidity and mortality of the disease	10%	20	0 to 20	
Therapeutic benefit	Magnitude of benefit	20%	20	0 to 40	
Safety	Risks of using the drug are taken into consideration	10%	20	0 to 20	
Cost impact	Impact on organization's budget	20%	0	–40 to 40	
Patient values and preferences	More convenient method of dosing or administering drug	10%	0	0 to 20	
Therapeutic alternatives	Alternative drugs available on the formulary	10%	20	0 to 20	
Scoring Range		–20% to 100%		–40 to 200	
Overall Score*					

* **SCORE CALCULATION**: Select the appropriate score under "Score Definition." Enter this number in the "Score" column. Multiply this number by the "Weight (%)" for this category; enter the result in "Weighted Score." Divide this number in half and enter the result in "Final Score (%)." Add the numbers in the "Final Score (%)" column to obtain the "Overall Score." Note: The authors automated these calculations via an Excel spreadsheet.

SCORE SIGNIFICANCE: The scoring criteria aim to provide each requested drug an initial score that will result in one of the following decisions: expedited review if score is ≥ 70%; routine review if score is ≥ 30% and < 70%; rejection if score is < 30%.

† The choice of RR of 2 for safety is based on the "GRADE system," which the authors' hospital uses for grading quality of evidence.[16]

RCT = randomized controlled trial; RR = relative risk/risk ratio; SR = Saudi riyal.

We plan to utilize the tool in our committee to prioritize the drugs requested for formulary addition through an initial screening process. Each new drug requested will be assigned to one reviewer, typically a clinical pharmacist member of the CDES, and drugs will be classified accordingly to three main categories for evaluations. For drugs scoring less than 30%, a second independent clinical pharmacist will screen the drug. In cases of agreement with the first clinical pharmacist, the drug will be rejected and not evaluated further, and in cases of disagreement, the drug will be discussed in a CDES meeting to seek a consensus of CDES members on its evaluation status.

All drugs screened by the clinical pharmacist using the scoring criteria will be presented during the CDES meeting and will undergo discussion and consideration for disputes. This

	Score Definitions	Score*	Weighted Score*	Final Score (%)*	Comment and Justification
	Meta-analysis (score = 2) ≥ 2 RCTs or network meta-analysis or multicenter RCT with large study population (score = 1) 1 RCT (score = 0)				
	> 500 patients (score = 2) 101–500 patients (score = 1) 1–100 patients (score = 0)				
	Significant risk of morbidity or mortality (score = 2) Moderate morbidity (score = 1) Minimal morbidity (score = 0)				
	Significant potential additional therapeutic benefit (i.e., RR > 2 and clinically significant) (score = 2) Moderate potential additional therapeutic benefit (i.e., RR > 1 but ≤ 2 and clinically significant) (score = 1) Negligible potential additional therapeutic benefit (i.e., RR = 1 and no statistical significance) (score = 0)				
	No potential safety risks (i.e., RR = 1 and no statistical significance) (score = 2) Mild-to-moderate potential safety risks (i.e., RR > 1 but ≤ 2† or clinically significant) (score = 1) Significant potential safety risks (i.e., RR > 2 and clinically significant) (score = 0)				
	Significant decrease in budget (i.e., > 1,500,000 SR) (score = 2) Moderate decrease in budget (i.e., 250,000–1,500,000 SR) (score = 1) No significant increase or decrease in budget (i.e., 0–250,000 SR) (score = 0) Moderate increase in budget (i.e., 250,000–1,500,000 SR) (score = –1) Significant increase in budget (i.e., >1,500,000 SR) (score = –2)				
	≥ 3 of the following: easier route of administration, less frequent dosing, better tolerability, less monitoring (score = 2) ≤ 2 of the following: easier route of administration, less frequent dosing, better tolerability, less monitoring (score = 1) No difference (score = 0)				
	Innovative drugs despite presence of alternatives that improve patient clinical outcomes (score = 2) No alternatives on formulary (score = 1) Alternative agent of either different or similar pharmacological class available (score = 0)				

last step ensures the involvement of all committee members in the screening decision. For drugs that have been rejected, a summary of our justification for rejection will be sent to the requesting health care provider.

As demonstrated in our results, the reviewers reported that a short time was required to review a drug using the scoring tool, which is essential in a large institution such as ours with multiple formulary addition requests received on a regular basis. The easy, short, yet multifactorial tool would provide structure to prioritizing drugs for review that were previously left to an unsystematic approach.

Limitations

Our tool has several limitations:

1. **Subjectivity.** The group recognized the subjectivity of some of the factors in the tool, which may lead to variations in scoring for the same drug by different reviewers (e.g., precise quality of evidence, disease severity). However, the piloting phase proved successful: Although scores were slightly unequal between reviewers for the same drug, the reviewers classified the evaluated drugs in the same category 92% of the time.
2. **Score limited to one indication.** Drugs may return different scores based on different indications, as the level of evidence and availability of alternatives may

Table 2 Example of Scoring Tool Use for Drug Prioritization Review: Dexlansoprazole

Criterion	Description	Weight (%)	Weight	Range of Weighted Scores	
Body of evidence	Published scientific literature that provides evidence of the drug's benefits	10%	20	0 to 20	
Population	Size of the population that would benefit from treatment with the drug	10%	20	0 to 20	
Disease severity	Morbidity and mortality of the disease	10%	20	0 to 20	
Therapeutic benefit	Magnitude of benefit	20%	20	0 to 40	
Safety	Risks of using the drug are taken into consideration	10%	20	0 to 20	
Cost impact	Impact on organization's budget	20%	0	–40 to 40	
Patient values and preferences	More convenient method of dosing or administering drug	10%	0	0 to 20	
Therapeutic alternatives	Alternative drugs available on the formulary	10%	20	0 to 20	
Scoring Range		–20% to 100%		–40 to 200	
Overall Score*					

* See Table 1 notes for an explanation of the scoring calculations. The 60% score qualifies dexlansoprazole for routine review.

† The choice of RR of 2 for safety is based on the "GRADE system," which the authors' hospital uses for grading quality of evidence.[16]

GERD = gastroesophageal reflux disease; RCT = randomized controlled trial; RR = relative risk/risk ratio; SR = Saudi riyal.

differ for the same drug used for a different indication (e.g., canakinumab [Ilaris, Novartis] for pediatric juvenile rheumatoid arthritis versus cryopyrin-associated periodic syndromes). Therefore, when reviewing a drug it is essential to specify the indication for which the drug is requested.

3. **Generalizability of the tool.** The tool has limited applicability to oncology and orphan medications, which lack a body of evidence, are deficient in available alternatives, and have extreme cost impacts. We agreed to exclude these medications from our screening process and to work on developing a separate tool for these drugs.

USE OF THE TOOL BY OTHER INSTITUTIONS

We anticipate that other institutions may utilize our scoring tool by modifying the following factors to reflect their own settings:

	Score Definitions	Score*	Weighted Score*	Final Score (%)*	Comment and Justification
	Meta-analysis (score = 2) ≥ 2 RCTs or network meta-analysis or multicenter RCT with large study population (score = 1) 1 RCT (score = 0)	2	20	10%	
	> 500 patients (score = 2) 101–500 patients (score = 1) 1–100 patients (score = 0)	2	20	10%	
	Significant risk of morbidity or mortality (score = 2) Moderate morbidity (score = 1) Minimal morbidity (score = 0)	2	20	10%	
	Significant potential additional therapeutic benefit (i.e., RR > 2 and clinically significant) (score = 2) Moderate potential additional therapeutic benefit (i.e., RR > 1 but ≤ 2 and clinically significant) (score = 1) Negligible potential additional therapeutic benefit (i.e., RR =1 and no statistical significance) (score = 0)	1	20	10%	Dexlansoprazol is superior in control of GERD symptoms compared to esomeprazole. However, there is no difference in healing or maintenance of healing.
	No potential safety risks (i.e., RR= 1 and no statistical significance) (score = 2) Mild to moderate potential safety risks (i.e., RR > 1 but ≤ 2† or clinically significant) (score = 1) Significant potential safety risks (i.e., RR > 2 and clinically significant) (score = 0)	2	20	10%	
	Significant decrease in budget (i.e., > 1,500,000 SR) (score = 2) Moderate decrease in budget (i.e., 250,000–1,500,000 SR) (score = 1) No significant increase or decrease in budget (i.e., 0–250,000 SR) (score = 0) Moderate increase in budget (i.e., 250,000–1,500,000 SR) (score = –1) Significant increase in budget (i.e., >1,500,000 SR) (score = –2)	0	0	0%	
	≥ 3 of the following: easier route of administration, less frequent dosing, better tolerability, less monitoring (score = 2) ≤ 2 of the following: easier route of administration, less frequent dosing, better tolerability, less monitoring (score = 1) No difference (score = 0)	0	0	0%	
	Innovative drugs despite presence of alternatives that improve patient clinical outcomes (score = 2) No alternatives on formulary (score = 1) Alternative agent of either different or similar pharmacological class available (score = 0)	2	20	10%	A dual-delayed-release formulation that results in two distinct peaks.
				60%	

1. **Population.** They can determine the prevalence and incidence of the disease and estimate the total number of patients seen at their institution by utilizing real data from the hospital's health information system and/or drug utilization data for a drug used to treat the same disease.
2. **Cost impact.** They can base the financial effect on their drug acquisition costs, expenditures, and currency.
3. **Score cutoff limits.** They may chose not to reject drugs that score less than 30% and may simply use that score to place the drug further down in the queue.

CONCLUSION

We believe that the scoring tool for prioritization of drugs is effective for screening new drugs for formulary addition and will aid in optimizing institutional resources. Future research and efforts should aim to validate this tool and to assess the impact of collaborative efforts in standardizing evaluation and screening processes of new drugs for formulary addition and in facilitating the workflow of P&T committees.

Table 3 Piloted Drugs Being Requested for Addition and in Queue for Evaluation And Their Score by Two Independent Reviewers Using the Proposed Tool

Drugs in Queue for Evaluation	Reviewer 1 Score (%)	Reviewer 2 Score (%)	Category Assigned
Fluticasone furoate/vilanterol trifenetrate (Breo Ellipta, GlaxoSmithKline)	40%	45%	Routine review
Pirfenidone (Esbriet, Genentech)	25%	45%	Disagreement*
Linagliptin (Tradjenta, Boehringer Ingelheim)	45%	35%	Routine review
Cefixime	45%	45%	Routine review
Canakinumab (Ilaris, Novartis)	25%	10%	Rejected
Bupropion (mental health)	20%	20%	Rejected
Evolocumab (Repatha, Amgen)	30%	50%	Routine review
Ustekinumab (Stelara, Janssen)	25%	25%	Rejected
Pitavastatin	20%	15%	Rejected
Dexlansoprazole (Dexilant, Takeda Pharamaceuticals)	60%	55%	Routine review

* See "Results" section for comments on how the dispute was handled.

Table 4 Comparison of Outcomes for Three Selected Drugs That Had Been Evaluated Previously by the CP&T Committee and the Category Assigned After Using the Tool

Drugs*	Reviewer 1 Score (%)	Reviewer 2 Score (%)	Category Assigned Using the Tool	Status After Full Evaluation By CP&T Committee
Bisoprolol	25%	25%	Rejected	Rejected
Duloxetine	25%	20%	Rejected	Rejected
Apixaban (Eliquis, Bristol-Myers Squibb)	70%	55%	Expedited review	Approved

* Drugs that had already been evaluated by our committee in the past, their scores using the tool proposed by two independent reviewers, and the decision made by the committee.

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