P&T Committee and monograph preparation

Dr. Coreen Montagna, PharmD
Managed Care

- Managed care is based on the same basic principle as a household budget. Money in the form of monthly premiums comes in, and money in the form of payments for care and administrative costs goes out.

- In our market, most insurance is provided by non-profit organizations. This means we are not answerable to shareholders to make a profit. However, we still cannot spend more than we take in, and excess profit in a given year is put into reserves in case of catastrophically expensive events.

- The goal is to make sure that members have access to appropriate medications while also maintaining a reasonable cost (premium).
Managed Care

- In the U.S., cost of care has been a taboo subject for some time.
- Patients and providers are insulated from the true cost of therapies.
- Pharmaceutical marketing causes an increased demand for higher profit therapies that may have no or marginal benefit over existing less expensive therapies.
- Our fragmented system of care causes much overutilization and duplication of care.
Managed Care

- For these reasons, insurance companies, and Federal agencies, use utilization management techniques to try to control the soaring cost of healthcare.
- Insurance premiums (and Medicare taxes) are directly linked to how much is spent on healthcare. If you spend more than you have, the next year the cost is going to be higher.
- Allowing everyone to have everything they want has consequences- rising premiums. And when premiums rise, employers are increasingly likely to ask employees to pay a larger cost, or to drop coverage completely.
P&T Committees

- The purpose of a P&T Committee (Pharmacy and Therapeutics) is to take available information about drug therapies and use that to make determinations about how and when the therapy should be covered.
- Information that may be used can include clinical trials and FDA documents, comparative studies, cost and rebate information, and utilization data.
P&T Committees

- The Committee must assess whether or not a new therapy is clinically useful, and how it compares to existing therapies.
- The Committee also regularly evaluates existing drug categories for opportunities to lower patient cost while preserving appropriate care.
P&T Committees

- The Committee will typically advise the plan on items such as tier placement of medications, utilization management (such as requiring Prior Auth or Step Therapy and what that criteria should be), and patient safety and educations programs.
- P&T Committees typically consist of community physicians of various specialties and community pharmacists.
P&T Committees

- The P&T Committee is routinely presented with utilization information from different drug classes, and they may use this information to suggest new programs.
- When new safety information arises, such as with the COX-2 inhibitors, our utilization data is useful in identifying which members may have taken these medications, and allows us to target them for informational mailings.
New Drug Reviews

- When a new drug comes to the market, it is presented to the P&T Committee for evaluation.
- The Committee will recommend how and when the plan should cover the medication.
- The primary concern will be real world applicability and how the product compares to existing therapies.
New Drug Reviews

- A new drug can be:
  - The first drug available to treat a disease
  - A new drug in an existing class
  - A new dosage form of an existing drug
  - A patent extension

- The Committees concerns will vary depending on which category the new drug falls into.

- We will review how each of these examples would be presented to the Committee.
The first drug available to treat a disease

- When a drug is the first FDA approved treatment option for a disease, there is typically no comparison data.
- There may be drugs that have been used off-label to treat the same disease.
- Primary concerns will involve efficacy, side effects, and identifying which patient populations stand to benefit the most from therapy.
A new drug in an existing class

- Typically, the product will have one or two unique features that the company will try to use to differentiate themselves from other products in the class. For example, the new drug might have a simpler dosing schedule, or a lower incidence of a class wide side effect.

- Primary concerns will involve efficacy, tolerability, and cost compared to other drugs in the class.
A new dosage form of an existing drug

- Example - a drug previously available in capsule form may become available in liquid form.
- Typically, new dosage forms are an issue of convenience.
- Primary concerns will involve cost verses existing dosage form, tier placement of existing dosage form, and convenience.
At the bottom of the heap are the obvious patent extensions. These typically take the form of modified release versions (Paxil CR), isomers (Clarinex), pro-drugs (Pristiq), combinations (Caduet), or reformulations to prevent generic substitution (Tricor). Unless there is a clear advantage to the change, such products are not typically endorsed by the P&T Committee for preferential tier placement.
New Drug Reviews

- See additional handouts for example new drug reviews.
- Mozobil, Bystolic, Exelon Patches, and Pristiq.
Assignment

- Complete a new drug review on one of the following medications:
  - Ampyra (dalfampridine)
  - Prolia (denosumab)
- Submit the assignment via the electronic dropbox-assignments due by midnight 10/4/10.
- Graded out of 10 possible points
- For questions, email me at csicseri@buffalo.edu