

## Coverage of Erectile Dysfunction Therapies Within the Managed Care Community

*An interview with James T. Kenney, Jr., RPh, MBA, Pharmacy Operations Manager, Harvard Pilgrim Health Care, Wellesley, Massachusetts*

*Mr. James T. Kenney, Jr., has more than 25 years of experience in chain and independent retail pharmacy, hospital pharmacy, and managed care pharmacy. He is Pharmacy Operations Manager for Harvard Pilgrim Health Care, an early pioneer in the provision of high-quality medical care within a managed care delivery system. At Harvard Pilgrim Health Care, a combination staff, group, and IPA model HMO based in Boston, Mr. Kenney is responsible for managing the corporate pharmacy contracting program and is a member of the Corporate Pharmacy and Therapeutics Committee.*

**AJMC:** *Do most managed care delivery systems offer clinical pathways for the treatment of ED?*

**Mr. Kenney:** If a health plan provides coverage for the treatment itself, it would likely have clinical pathways for the treatment and management of the condition. If a health plan does not cover any of the therapies, it probably has not gone to the trouble of putting together a guideline.

**AJMC:** *In the absence of a pathway, what factors would likely influence prescribing decisions?*

**Mr. Kenney:** Safety, efficacy, and cost would be paramount concerns.

**AJMC:** *How does the concept of medical necessity as a determinant of coverage apply to non-life-threatening problems such as ED?*

**Mr. Kenney:** Medical necessity can be a difficult term to define. Our objective as a plan is clearly to restore and maintain the overall health of our patients. We have not typically dealt with pharmaceutical products along the lines of medical necessity vs lifestyle—we have not employed the lifestyle medication category to review products. All medications are reviewed similarly by the P&T [Pharmacy and Therapeutics] Committee when considered for formulary placement.

**AJMC:** *What are some of the factors that influence formulary decisions for non-life-threatening conditions?*

**Mr. Kenney:** Factors are consistent with all products—efficacy, safety, appropriate use, and compliance as well as costs and best practices for different therapies.

**AJMC:** *One study we've cited in this issue reports that values play a significant but unspoken role in coverage decisions for new therapies. What is your perspective on this?*

**Mr. Kenney:** Our view was that sildenafil was in a unique position as a chemical entity with no other product in that category as an oral treatment of the condition. Therefore, it was considered for formulary inclusion. The concept of value was not raised by the committee. We did, however, set a coverage limit of 4 tablets per 30-day supply, comparable to the limits already established for suppositories and injectables.

**AJMC:** *Is it contradictory to cover vacuum devices for ED but not oral agents?*

**Mr. Kenney:** If a health plan is covering treatment options for a particular disease that are less convenient, it would be contradictory to deny coverage for more convenient options, provided that they were reasonable alternatives. Currently, we cover each of the pharmacologic treatments—suppositories, injections, and tablets—as part of our drug benefit.

**AJMC:** *Is there an inherent socioeconomic bias in tiered formulary systems?*

**Mr. Kenney:** The intent of the formulary process and the tiered benefit is to manage the total drug expense rather than selectively target patients who might be disadvantaged. In fact, a reasonable number of drugs covered in each of the therapeutic categories would afford the vast majority of patients easy access to drugs listed on the first or second tiers. A majority of the time, the patient will have several options. The third tier provides another option that patients could discuss with their physicians if the copay-

ment was a cause of concern. Currently, sildenafil is a second-tier drug in our plan.

**AJMC:** *How does ED compare with other diseases that compete for limited resources?*

**Mr. Kenney:** It's in the mix. We clearly have limited resources, both on the medical and pharmaceutical side. The formulary definitely helps us manage that limited resource.

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**AJMC:** *Has direct-to-consumer advertising influenced your health plan's ED costs? Have you devised a way to track its impact?*

**Mr. Kenney:** One would assume that raising awareness would affect utilization, but we're not tracking that. It would be very difficult to assess and would also involve questioning patients, which wouldn't be a positive experience for the patients or the health plan, particularly around the subject of ED. But given the initial attention given to sildenafil through the media, there wasn't a lot of DTC [direct-to-consumer] advertising necessary. Recently, utilization has decreased and competitors are coming to the market with new oral agents, which is why we are seeing increased advertising now.

**AJMC:** *Do you prepare your providers for responding in a responsible manner to patient demands for advertised drugs?*

**Mr. Kenney:** Not directly but we routinely provide treatment guidelines and algorithms to help them manage various diseases. Certainly, this information would help a physician manage all aspects of the disease, including the impact of DTC advertising. In addition, the 3-tier drug benefit may also provide assistance to the physician in managing patient demand for products.

**AJMC:** *Does successful treatment of ED prevent other healthcare expenditures?*

**Mr. Kenney:** Intuitively, you would believe patients would have other negative health issues resulting from the condition—depression, anxiety—that would obviously cause an increase in expense in other components of healthcare. However, if the ED is treated successfully, it is possible that these other related conditions may be resolved as well.

**AJMC:** *One recent Newsweek survey cites drug coverage as being the most important factor in determining consumers' level of satisfaction with a health plan. Has that been your experience?*

**Mr. Kenney:** I don't find that surprising. Historically, when we surveyed

patients for satisfaction with our health plan, 20% to 25% of the write-in comments specifically mentioned the drug benefit as being of value, even though there weren't any questions in the survey itself about the drug benefit. This goes back 10 or 15 years. It's been a very popular part of the benefit package.

**AJMC:** *How do you determine if ED is an important disease to plan members? Would such a finding influence coverage decisions?*

**Mr. Kenney:** The view of the P&T Committee was that ED products were valuable therapies that should be offered to patients who have the drug benefit. However, the most important factor for a managed care plan is to properly diagnose the condition and perhaps rule out other causes such as medications that can lead to ED. Simply changing a medication can solve the problem rather than having to add another therapy to the patient's regimen. The condition itself may be indicative of an underlying medical condition that has not been detected. We have a formal diagnostic process that we encourage physicians to go through to identify a correctable cause of the problem. Another issue relates specifically to use of sildenafil. The contraindications to patients taking nitrate medication should be evaluated when patients are considered for therapy.