

Covering Lif

After listing Viagra, the Canadian Armed Forces commissioned a study to test how effectively coverage was being approved. The process has since been streamlined.

By Tom Smiley and Alan Gervais

With the approval of several new prescription medications that many plan sponsors have labelled “lifestyle drugs,” the formulary management decision-making process has become much more challenging over the past few years. Examples of so-called lifestyle drugs include Propecia for male-pattern baldness, Xenical for weight loss, Viagra for erectile dysfunction and most recently Botox for treatment of crow’s feet around the eyes.

Traditionally, lifestyle drugs come with a high price tag, and plan sponsors are often reluctant to pay for medications that may further inflate prescription drug plan payouts when they are perceived not to afford any benefit to the health or productivity of their plan members. But is it wise to make an initial judgment based on that perception? Should plan sponsors consider the potential benefits to employees, or at least re-evaluate the situation after the medication has been on the market for a length of time?

Let’s first define what we mean by lifestyle drugs. There are two definitions that encompass most preconceived notions.

The first suggests that lifestyle drugs do not afford any real health benefits to those people taking them. For example, although Propecia and Botox may help improve the self-image of people taking these medications, they appear to afford little benefit in terms of improved health or treat-

ment of any particular medical condition.

The second definition suggests that lifestyle drugs treat medical problems originating from a person’s lifestyle choices. Zyban is effective for helping people quit smoking. It falls under this classification. This definition differs from the first because people who quit smoking can expect health benefits, or at least a reduced risk of negative health outcomes in the future. Plan sponsors include drugs for their formulary that fit this second definition more often.

Formulary management is a challenge for any plan sponsor. The methods by which we analyze appropriateness for formulary inclusion are often biased by preconceived notions or information obtained through the media. With drugs like Zyban, some may take the view that “you got yourself into this position, I’m not going to bail you out.”

Evidence suggests however that savings related to reduced absenteeism, increased productivity and reduced life insurance premiums resulting from employees quitting smoking far outweigh the costs associated with counseling programs and associated quit-smoking aids.

In short, it is important to gather all available information when evaluating the risks, benefits and cost-effectiveness of so-called lifestyle medications for formulary inclusion consideration. It is also critical, when attempting to maximize the cost-effectiveness of the prescription drug benefits plan, to revisit and fine tune choices when new information becomes available. A study recently completed by the Canadian Armed Forces illustrates that point.

THE CAF STORY

Viagra was included as a “special authorization” benefit of the Canadian Armed Forces prescription drug plan in July 2000. Criteria for payment of a claim for Viagra consisted of a visit to a specialist in the area of erectile dysfunction (e.g., a urologist, psychiatrist or internal medicine specialist), with a maximum benefit set at 12 tablets for any two-month period.

The population under review consisted of a relatively young healthy male population of the Canadian Armed Forces. In March 2001, a study was commissioned to assess the benefits and challenges of the Viagra approval process. The charts of the 163 servicemen receiving

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approved prescriptions for Viagra between July 2000 and March 2001 were reviewed.

The analysis in these charts includes a period of one year before and after receiving an initial prescription for Viagra. Factors analyzed included:

- The cause of erectile dysfunction (and level of agreement between general practitioner and specialist).
- The effect of the Viagra policy on the number of visits to a specialist or general practitioner, and the length of time it took for referral, consultation and actual filling of a prescription for Viagra after the policy was put in place.

In many men, erectile dysfunction results from a combination of factors that may include problems related to blood flow, hormones, nerves and/or psychology. Often erectile dysfunction is defined as either organic (vascular, endocrinologic, neurogenic) or psychogenic in origin. Many cases are classified as mixed (both organic and psychogenic).

The first table (see “Diagnosis of erectile dysfunction made by a specialist or general practitioner,” below) lists the causes of erectile dysfunction according to the level of agreement between the specialist or general practitioner group. Note that the specialist group diagnosed 56 of the 150 men reviewed with an organic cause of erectile dysfunction. The general practitioner group classified these same men as having an unknown cause of erectile dysfunction.

We also observe that the general practitioner group did not diagnose the cause of erectile dysfunction in approximately 68% of the sample (102 out of 150 patients). Whereas the specialist did not diagnose the cause in only 6% (nine out of 150 patients) of the sample.

In spite of these differences, further analysis of the patients’ charts revealed that the likelihood of eventually receiving a prescription for Viagra did not change as a result of visiting a specialist. Therefore, there would appear to be no rationale for withholding a prescription for Viagra until a specialist was seen.

The second table (see “Time to referral, consultation and Viagra prescription after policy put in place,” page 109) outlines the challenges presented to men needing to see a specialist before receiving a prescription.

There was a mean wait for a Viagra prescription of approximately 32 weeks from the first diagnosis of erectile dysfunction. Men scheduled to see a psychiatrist waited an average of greater than one year before receiving a prescription.

In essence, the outcome of receiving a Viagra prescription did not change—just the extra time to get the prescription, and the public costs incurred through specialist referral. Furthermore, feedback from doctors has not been positive.

Some general practitioners did not understand why a specialist appointment was necessary if they did not identify an underlying ailment. They were of the opinion that sending the patient to see a specialist anyway represented a waste of time and resources. Also, some of the men were already taking Viagra with successful results, and a trip to a specialist was seen only as a “rubber stamp” to get the medication approved for payment. Finally, one specialist refused to see any of the referred patients unless they had already been taking Viagra. If the medication was not effective, then the specialist would look for an underlying cause.

With all of these considerations in mind, the Canadian Armed Forces has decided to remove the criteria requiring patients to visit specialists before deeming Viagra a benefit. The quantity-limit criteria of 12 tablets every two months has been maintained. The criteria should not affect the general practitioner’s practice of referring a patient to a specialist if an underlying diagnosis of the cause of erectile dysfunction has not been identified.

DIAGNOSIS OF ERECTILE DYSFUNCTION MADE BY A SPECIALIST OR GENERAL PRACTITIONER

		Cause of ED according to specialist				Total
		Organic	Psychogenic	Mixed	Unknown	
Cause of ED according to general practitioner	Organic	16	0	2	2	20
	Psychogenic	6	0	3	1	10
	Mixed	14	0	4	0	18
	Unknown	56	8	32	6	102
	Total	92	8	41	9	150

TIME TO REFERRAL, CONSULTATION AND VIAGRA PRESCRIPTION AFTER POLICY PUT IN PLACE

Variable	# of men	minimum	maximum	mean (standard deviation)
Length between ED diagnosis and Viagra prescription (in weeks)	152	0	507	32.27 (61.39)
Length between consultation with a psychiatrist to Viagra prescription (in weeks)	10	16	182	68.64 (54.39)
Length between referral and consultation to an ED specialist (in weeks)	125	0	52	7.16 (7.20)
Urologist	110	0	52	7.54 (7.45)
Psychiatrist	7	0	14	5.51 (5.20)
Internist	6	0	9	3.33 (3.10)
Other	2	1	6	3.43 (3.43)

Note: 16 patients have been omitted from analysis because they had either seen a specialist or received a prescription for Viagra before the analysis began.

COST EFFECTIVENESS

This study provides food for thought with respect to implementing the most cost-effective formulary choices, or putting effective criteria in place. Keeping on top of newly published information that may influence formulary choices is also important.

For example, there is evidence to suggest that successful treatment of erectile dysfunction may result in improvement in depression scores and quality of life ("Lower self-reported depression in patients with erectile dysfunction after treatment with sildenafil," by Matthias Muller and Otto Benkert, published by the *Journal of Affective Disorders* and "The cost-effectiveness of sildenafil," by Kenneth Smith and Mark Roberts, published by *Annals of Internal Medicine*). Smith and Roberts's article concluded that the cost-effectiveness of Viagra treatment compared favourably with that of accepted treatments for other medical conditions.

Furthermore, the fear of costs going through the roof with the introduction of Viagra have not been realized. Aggregate information gathered by RX Information Center Ltd. from three private Canadian insurers (representing over 66,000 patients) suggest that on average, Canadian men using the medication take one tablet every week or two weeks and renew their prescriptions only twice over a seven- or 12-month period.

The most challenging question for formulary decision-makers is where to draw the line on formulary inclusion. Your first step is to develop a philosophy about what is included in your drug plan.

Different levels of formulary coverage have evolved over the years. Many plans have an open formulary that allows any new product on the market into the formulary. The other extreme is a closed or frozen formulary that does not allow for any new products.

Some plan sponsors are opting for a controlled formu-

lary that includes evaluation of a new product by an independent source, with new additions to the formulary made at approximately three-month intervals. Cost sharing and capping of dollars allowed, or quantity allowed per time period are additional tools for the plan sponsor who does not want to deny outright coverage.

There are plans that require qualifying criteria or prior authorization by doctors before particular medications are paid for. However, any such criteria should be based on sound evidence gathered from clinical trials. Therefore the independent source should have expertise in this area. Criteria need to be re-evaluated at regular intervals to ensure that they are accomplishing the intended goals.

When considering medications for formulary inclusion, it is important to consider all available relevant information with reference to their potential value to the health and wellness of employees. The Canadian Forces experience with criteria set for Viagra, and newly published information regarding cost-effectiveness and utilization of the medication illustrates the extreme importance of regular re-evaluation of formulary decisions. A benefits formulary should be a dynamic document that evolves with the aid of a structured evaluation process that is tailored to your organization's needs.

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