

**MEMORANDUM**

**DEPARTMENT OF HEALTH AND HUMAN SERVICES  
PUBLIC HEALTH SERVICE  
FOOD AND DRUG ADMINISTRATION  
CENTER FOR DRUG EVALUATION AND RESEARCH**

**PID#:** D030559

**DATE:** December 7, 2004

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**TO:** Solomon Iyasu, MD, MPH  
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**SUBJECT:** One Year Post-Pediatric Exclusivity Postmarketing Adverse Event Review: Drug Use Data  
Orlistat (Xenical®, NDA 20-766)  
Pediatric Exclusivity Approval Date: September 9, 2003

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**EXECUTIVE SUMMARY**

The increasing prevalence of childhood obesity throughout the United States has become a major public health concern due to its association with various health-related outcomes, including type 2 diabetes mellitus, cardiovascular disease as well as social and psychological problems. While pharmacological therapy in the management of pediatric obesity has been considered as an additional approach to manage childhood obesity, it is likely to entail long-term exposure to the potential adverse effects of medication used. The use of therapeutic interventions, therefore, requires a rigorous evaluation of the risks and benefits.

This consult examines the drug use for orlistat in the pediatric population (0-16 years), with primary focus on patterns of use one year before and one year following the granting of Pediatric Exclusivity on September 9, 2003. Proprietary drug use databases licensed by the Agency were used to conduct this analysis. The IMS Health, National Sales Perspectives™ was used to determine the various retail and non-retail channels of distribution. Since the majority of use for this product occurs in the outpatient setting, we further examined the utilization patterns for

orlistat focusing on the outpatient setting. Outpatient use was measured by two IMS Health audits, the National Prescription Audit *Plus*<sup>™</sup> (NPA *Plus*<sup>™</sup>) and the National Disease and Therapeutic Index<sup>™</sup> (NDTI<sup>™</sup>), along with prescription claims for a 36-month period of time from Caremark (Dimension Rx<sup>™</sup>).

There was an overall decrease in prescriptions dispensed for Xenical® from an estimated 1.6 million prescriptions in the 12-month period ending in September 2002 (10/01 – 9/02) to 1 million prescriptions in the 12-month period ending in September 2004 (10/03 – 9/04). This represented a 38% decrease in prescriptions dispensed for this product.

In general, prescribing patterns for orlistat dispensed in outpatient retail pharmacy settings showed relatively little change across provider specialties from October 2001 through September 2004. The top three prescribing specialties for this product were internal medicine (31.1%) family practice (26.9%), and osteopathic medicine (9.3%) in the most recent 12-month period ending in September 2004. The pediatric specialty represented approximately 1% of prescriptions dispensed for this product.

According to IMS Health, NDTI<sup>™</sup>, the diagnosis, or indication, most frequently linked to Xenical® use in the adult population (17 years and above) from January 2004 through September 2004, inclusive, was “obesity” (ICD-9 code 278.0), accounting for 79% of the total Xenical® mentions during office-based physicians visits.

Overall, the use of Xenical® in the Caremark system as well as in IMS HEALTH data sources appears nearly exclusive to the adult population. Less than 1% of the total prescription claims for Xenical® were for persons aged 1-16 years. Use has been decreasing in both pediatric and adult populations over the past three years.

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## INTRODUCTION

On January 3, 2001, Congress enacted the Best Pharmaceuticals for Children Act (BPCA) to improve the safety and efficacy of pharmaceuticals for children. Section 17 of that act requires the reporting of adverse events associated with the use of a drug in children during the one year following the date on which the drug received marketing exclusivity. In support of this mandate, the FDA is required to provide a report to the Pediatric Advisory Subcommittee of the Anti-Infective Drugs Advisory Committee on the drug utilization patterns and adverse events associated with the use of the drug on a quarterly basis. This review is in addition to the routine post-marketing safety surveillance activities the FDA performs for all marketed drugs.

Obesity has become a major public health concern in the general population as well as in children.<sup>1</sup> Childhood obesity is associated with short-term and long-term outcomes, including type 2 diabetes mellitus, cardiovascular disease as well as social and psychological problems. Over the past three decades, the prevalence of overweight preschool children ages 2 to 5 years and children ages 6 to 11 years has more than doubled and it has more than tripled for adolescents ages 12 to 19 years.<sup>2</sup> These trends reflect those in the adult population in the U.S.

The current clinical approach to management of pediatric obesity is behavioral therapy toward changing diet and physical activity.<sup>3</sup> Yet, given the increasing prevalence of childhood obesity throughout the United States and its substantial health risks, pharmacological treatment may also provide an additional new intervention strategy to address this epidemic. Currently, there are no drugs indicated to treat obesity in children and the role of pharmacological therapy in the management of pediatric obesity has been controversial.<sup>3</sup> This is mainly because obesity is a chronic problem and, as such, is likely to require long-term exposure to medication, with the potential for adverse effects of medication used.

Orlistat (Xenical®, NDA 20-766) was approved on April 23, 1999 for the treatment of obesity. Currently, Xenical® is indicated for obesity management including weight loss and weight maintenance when used in conjunction with a reduced-calorie diet.<sup>4</sup> Xenical® is also indicated for reducing the risk for weight regain after prior weight loss. Xenical® is indicated for obese patients with an initial body mass index (BMI)  $\geq 30$  kg/m<sup>2</sup> or  $\geq 27$  kg/m<sup>2</sup> in the presence of other risk factors (e.g., hypertension, diabetes, dyslipidemia).

Orlistat is a reversible inhibitor of lipase enzyme in the gastro-intestinal track that reduces the absorption of triglycerides with very minimal systematic absorption. The resulting caloric deficit may have a positive effect on weight control. At the recommended therapeutic dose of 120 mg three times a day, Xenical® inhibits dietary fat absorption by approximately 30%. Xenical® should be taken with each main meal containing fat. The dose of Xenical® may be omitted if a

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<sup>1</sup> Committee on Prevention of Obesity in Children and Youth. Preventing childhood obesity: Health in the balance. Washington DC: National Academy Press, 2005. Available at:

<http://books.nap.edu/books/0309091969/html/index.html>. Last accessed: Dec 6, 2004

<sup>2</sup> Ogden CL, Flegal KM, Carroll MD, Johnson CL. Prevalence and trends in overweight among US children and adolescents, 1999-2000. JAMA 2002; 288(14):1728-32. PMID: 12365956

<sup>3</sup> Daniels S. Pharmacological treatment of obesity in paediatric patients. Paediatr Drugs 2001;3(6):405-10. PMID: 11437185

<sup>4</sup> PDR ® Electronic Library™, accessed November 2004.

meal is skipped or does not contain fat. The product is available in 120 mg capsules and is supplied in a bottle of 90 capsules.

The efficacy and safety of Xenical® for obesity management have been evaluated in controlled studies in obese adults as well as in adolescent patients aged 12 to 16 years. However, safety and efficacy have not been established in pediatric patients younger than 12 years old. The Pediatric Exclusivity Board of the FDA granted pediatric exclusivity for orlistat (Xenical®, NDA 20-766/S-018) on September 9, 2003. To date, there are no generic competitors for this product.

This review describes outpatient drug use patterns for orlistat in the pediatric population as well as in the adult population in the years prior to and subsequent to the granting of pediatric exclusivity. Proprietary drug use databases licensed by the Agency were used to conduct this analysis.

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## **DATA SOURCES**

Sale of these products by number of bottles and capsules sold from the manufacturer to various retail and non-retail channels of distribution were analyzed using the IMS Health, National Sales Perspectives™ (Table 1). Since the majority of use for this product occurs in the outpatient setting (95% of all bottles and capsules sold were to outpatient pharmacies during October 2003 through September 2004), we further examined the utilization patterns for orlistat focusing on the outpatient setting. Outpatient use was measured by two IMS Health audits, the National Prescription Audit *Plus*™ (NPA *Plus*™) and the National Disease and Therapeutic Index™ (NDTI™), along with prescription claims for a 36-month period of time from Caremark (Dimension Rx™).

**Table 1. Sale of Xenical Bottles (Eaches) and Capsules (Extended Units) Sold to Retail and Non-Retail Channels of Distribution During October 2003 – September 2004 in IMS Health, National Sales Perspectives™**

<b>Retail and Non-Retail Distribution Channels</b>	<b>Eaches (000)</b>	<b>%</b>	<b>Extended Units (000)</b>	<b>%</b>
<b>Retail</b>	<b>866,700</b>	<b>94.6</b>	<b>78,012</b>	<b>94.6</b>
Chain Stores	455,500	49.7	40,994	49.7
Independent	192,100	21	17,293	21
Mail Service	122,200	13.3	11,002	13.3
Food Stores	96,900	10.6	8,723	10.6
<b>Non-Retail</b>	<b>50,100</b>	<b>5.5</b>	<b>4,402</b>	<b>5.3</b>
Clinics	17,100	1.9	1,430	1.7
Long-Term Care	11,500	1.3	1,037	1.3
Federal Facilities	9,300	1	841	1
Non-Federal Hospitals	5,900	0.6	527	0.6
HMO	2,800	0.3	255	0.3
Home Health Care	2,600	0.3	232	0.3
Miscellaneous-Other	600	0.1	51	0.1
Miscellaneous-Universities	200	0	17	0
Miscellaneous - Prisons	100	0	12	0
<b>Total</b>	<b>916,900</b>	<b>100</b>	<b>82,413</b>	<b>100</b>

\* zero means less than 500 total projected

National Sales Perspectives™ Retail and Non-Retail, October 2003 – September 2004, Extracted November 2004.  
Original File: 0411xen3.dvr

## ***I. OUTPATIENT DRUG USE***

### ***IMS HEALTH, NATIONAL PRESCRIPTION AUDIT PLUS™ (NPA PLUS™)***

NPA Plus™ measures the retail dispensing of prescriptions, or the frequency with which drugs move out of retail pharmacies into the hands of consumers via formal prescriptions. These retail pharmacies include chain, independent, food store, mail order, discount houses, and mass merchandiser pharmacies, as well as nursing home (long-term care) pharmacy providers. Information on the specialty of the prescribing physician can also be collected, except for in the long-term care and mail order pharmacy settings.

The number of dispensed prescriptions is obtained from a sample of approximately 22,000 pharmacies throughout the U.S. and projected nationally. The pharmacies in the database account for approximately 40% of all pharmacy stores and represent approximately 45% of prescription coverage in the U.S.

Data for this analysis include prescriptions dispensed for orlistat from October 1, 2001 to September 30, 2004, inclusive.

### ***Caremark DIMENSION RX™***

Caremark is one of the largest pharmacy benefit manager (PBM) companies in the US, currently covering over 70 million lives, and processing over 545 million prescription claims annually. Dimension Rx™ accesses a subset of total Caremark claims, representing over 450 million prescription claims annually. People whose claims are processed by Caremark are covered under various types of insurance plans, including health maintenance organizations (HMOs), employers' self-insured health plans, selected managed care plans, and other selected traditional health insurers. Caremark manages prescription claims for people that are geographically dispersed and includes special populations such as the elderly, children, and women of childbearing age. The representativeness of those included in Caremark to all persons receiving dispensed prescriptions in the U.S., however, is not known.

For this analysis, annual prescription claims in the Caremark system were examined from November 1, 2001, to October 31, 2004, inclusive.

### ***IMS HEALTH, NATIONAL DISEASE AND THERAPEUTIC INDEX™ (NDTI™)***

The National Disease and Therapeutic Index™ (NDTI™) is an ongoing survey designed and conducted by IMS Health to provide descriptive information on the patterns and treatment of disease encountered in office-based practice in the continental U.S. by collecting data on drug products mentioned during visits to office-based physicians. The data are gathered by a panel of roughly 2,000 – 3,000 office-based physicians who complete and submit a survey of their practice patterns to IMS Health for two consecutive days per quarter. These data may include profiles and trends of diagnoses, patients, and treatment patterns and are collected and projected nationally to reflect national prescribing patterns.

NDTI™ uses the term drug uses for mentions of a drug in association with a diagnosis during an office-based patient visit. This term may be duplicated by the number of diagnosis for which the drug is mentioned. It is important to note that a drug use does not necessarily result in prescription being generated. Rather, the term indicates that a given drug was mentioned during an office visit.

For this analysis, we examined annual mentions of orlistat during office-based physician visits during the time period from October 1, 2001 to September 30, 2004, inclusive.

## **RESULTS**

### **I. Dispensed Prescriptions**

There was an overall decrease in prescriptions dispensed for Xenical® from an estimated 1.6 million prescriptions in the 12-month period ending in September 2002 (10/01 – 9/02) to 1

million prescriptions in the 12-month period ending in September 2004 (10/03 – 9/04) (Table 2). This represented a 38% decrease in prescriptions dispensed for this product for that time period. It should be noted however, that the number of prescriptions dispensed for Xenical® has been continuously decreasing even prior to that time period.

**Table 2: Total Number of Prescriptions (TRX) Dispensed in Retail Pharmacies (Excluding Long-Term Care Channel) for Xenical® from October 2001 through September 2004**

	Oct 99 - Sep 00	Oct 00 - Sep 01	Oct 01 - Sep 02	Oct 02 - Sep 03	Oct 03 - Sep 04
<b>Xenical® TRX (000)</b>	2603	2084	1644	1349	1019

IMS Health, National Prescription Audit *Plus*™, October 2001 – September 2004, Extracted November 2004.  
Original file: 0411xen1.dvr

The top three prescribing specialties for orlistat were internal medicine (31.1%) family practice (26.9%), and osteopathic medicine (9.3%) in the most recent 12-month period ending in September 2004 (Table 3). The pediatric specialty represented approximately 1% of prescriptions dispensed for this product. In general, prescribing patterns for this product showed relatively little change across provider specialties from October 2001 through September 2004 (data not shown).

**Table 3: Total Number of Prescriptions (TRX) Dispensed for Xenical® by Physician Specialty (Excluding Long-Term Care and Mail Order Pharmacies) Between October 2003 Through September 2004**

Rank	Physician Specialty	TRX (000)	% of TRX
1	Internal Medicine	296,000	31.1
2	Family Practice	256,000	26.9
3	Osteopathic Medicine	88,000	9.3
4	Obstetrics/Gynecology	39,000	4.1
5	General Practice	37,000	3.9
6	Endocrinology	33,000	3.5
7	Unknown	28,000	3
8	Cardiology	22,000	2.4
9	Nurse Practitioner	20,000	2.1
10	Physician Assistant	12,000	1.3
11	Psychiatry	12,000	1.2
12	Gastroenterology	10,000	1
13	General Surgery	9,000	0.9
14	<b>Pediatrics</b>	<b>8,000</b>	<b>0.9</b>
15	Pulmonary Diseases	7,000	0.7
16	Emergency Medicine	7,000	0.7
17	Neurology	6,000	0.6
18	Internal Med/Pediatrics	5,000	0.6
19	Nephrology	4,000	0.5
20	Rheumatology	4,000	0.4
<b>TOTAL</b>		<b>949,000</b>	<b>100</b>

IMS Health, National Prescription Audit *Plus*™, October 2003 – September 2004, Extracted November 2004.  
Original file: 0411xen2.dvr

## II. Patient Demographics

Of the total prescription claims for Xenical® among an insured population managed by Caremark, almost 80% were for women and only 20% for men (Table 4).

Consistent with IMS Health data sources, the total number of claims for Xenical® in this population has also decreased from 95,527 to 79,097 between November 1, 2001 and October 31, 2004. This decline in claims was found for both men and women.

The majority of the prescription claims for Xenical® were for adults aged 17 and older. Less than 1% of the total prescription claims for Xenical® were for persons aged 1-16 years. Similar to the prescription claims for adults, the number of prescription claims for the pediatric population (age 1-16 years) also declined from 347 claims to 296 claims over that same time period. While prescription claims for the pediatric population represents a small percentage of the total prescription claims for Xenical®, the ratio of males to females was similar to the ratio found in the adult population (approximately 1:3). This ratio was also confirmed in the NDTI™

of Xenical® mentions during physician-office visits of adults during that time period (Table 5). Overall, the use of Xenical® in the Caremark system as well as in IMS HEALTH data sources appears nearly exclusive to the adult population, and use has been decreasing in both pediatric and adult populations over the past three years.

**Table 4: Total Number of Claims for Xenical® across three-12 month periods by age groups and gender from November 2001 – October 2004 from Caremark Pharmacy Benefit Manager Database**

Characteristics	Total Number of Claims - TRx (%)					
	Nov 01 – Oct 02		Nov 02 - Oct 03		Nov 03 - Oct 04	
	N	(%)	N	(%)	N	(%)
<b>Age (years)</b>						
1-16	<b>347</b>	<b>(0.4)</b>	<b>274</b>	<b>(0.3)</b>	<b>296</b>	<b>(0.4)</b>
Female	242	(0.3)	198	(0.2)	235	(0.3)
Male	105	(0.1)	76	(0.1)	61	(0.1)
17+	<b>95,180</b>	<b>(99.6)</b>	<b>88,996</b>	<b>(99.7)</b>	<b>78,801</b>	<b>(96.5)</b>
Female	73,421	(76.9)	69,130	(77.4)	61,268	(77.5)
Male	21,759	(22.8)	19,866	(22.3)	17,533	(22.2)
<b>TOTAL</b>	<b>95,527</b>	<b>(100)</b>	<b>89,270</b>	<b>(100)</b>	<b>79,097</b>	<b>(100)</b>

Caremark Dimension Rx™, Extracted December 2004

**Table 5: Projected Number of Total Mentions of Xenical® in office-based physician visits by gender for adults (17 years of age and older) over calendar year from 2001 to September 2004 from NDTI™**

XENICAL	Drug Appearances in thousands (%)*							
	Year 2001		Year 2002		Year 2003		YTD/9/2004	
<b>TOTAL</b>	<b>855</b>	<b>(100.0)</b>	<b>593</b>	<b>(100.0)</b>	<b>380</b>	<b>(100.0)</b>	<b>300</b>	<b>(100.0)</b>
<b>Female</b>	691	(80.9)	447	(75.4)	286	(75.5)	245	(81.6)
<b>Male</b>	164	(19.1)	146	(24.6)	93	(24.5)	55	(18.4)

IMS HEALTH, National Disease and Therapeutic Index, Extracted November 2004.

Original File: 0411Orlistat SxAg.dvf

CD-ROM Source: NDTI 6 Year 10/98 - 9-04.

No data is available for patients aged 1-16 years.

\* A drug appearance roughly translates to a mention of a drug during a patient visit.

Since NPA Plus™ does not include demographic information on patients for the entire time period of interest, we applied the proportions for demographic subgroups from Caremark to NPA

Plus™ data in an effort to approximate the number of prescriptions dispensed for Xenical® nationwide to children (Table 6). Using this approach, a total of 4,076 prescriptions for Xenical® are estimated to have been dispensed for persons aged 1-16 years in the U.S. during the time period from October 1, 2003 to September 30, 2004.

**Table 6: Estimated Nationwide Prescriptions Dispensed for Xenical® During October 2003 – September 2004 in the Pediatric Age Group (1-16)**

	Total Number of Prescriptions* Dispensed for All Age Groups <i>(from Table 2)</i>	% Pediatric Claims** (Ages 1-16 yrs) <i>(from Table 4)</i>	Estimated Number of Prescriptions Dispensed to the Pediatric Population (Age 1-16 yrs)
<b>TOTAL</b>	1,019,000	0.4	4,076

\*IMS Health, National Prescription Audit Plus™, October 2001 – September 2004, Extracted November 2004. Original File: 0411xen1.dvf.

\*\*Caremark Dimension Rx™, Extracted December 2004

### III. Indication for Use

According to IMS Health, NDTI™, the diagnosis, or indication, most frequently linked to Xenical® use in the adult population (17 years and above) from January 2004 through September 2004, inclusive, was “obesity” (ICD-9 code 278.0), accounting for 79% of the total Xenical® mentions during office-based physicians visits<sup>5</sup> (data not shown). Metabolic syndrome (ICD-9 code 277.7) and abnormal weight gain (ICD-9 code 783.1) accounted for 7% and 6% of the total Xenical® mentions during office-based physicians visits during that time period. Obesity diagnosis accounted for almost 90% of the of the total Xenical® mentions during office-based physicians visits during the calendar year 2003 (data not shown).

No pediatric use was recorded for Xenical® in sampled patient-physician encounters over the past three years.

## **DISCUSSION**

Based on the databases that were used for this consult, there was an almost 40% decrease in the prescriptions dispensed for Xenical® in adults (aged 17 years or older) in the last three years from the 12-month period ending in September 2002 to the 12-month period ending in September 2004. The number of prescriptions dispensed for Xenical® has been continuously decreasing even prior to that time period. The continual decline in this product is consistent with a general decline trend with other anti-obesity medications in recent years reported by

<sup>5</sup>IMS HEALTH National Disease and Therapeutic Index; Original File: NDTI OCTAP 11-23-04 D030559 Orlistat 0411Orlistat AgDx;; CD-ROM Source: NDTI 6 Year 10/98 - 9-04

Governale<sup>6</sup> in the Endocrinologic and Metabolic Drugs Advisory Committee Meeting of September 2004.

There was relatively little change in the prescribing patterns for Xenical® dispensed in outpatient retail pharmacy settings across provider specialties from October 2001 through September 2004. The two major prescribing specialties for these products were internal medicine and family practice accounting for almost 60% of the prescriptions dispensed. While we can only estimate the projected number of prescriptions for Xenical® dispensed to the pediatric population aged 1-16 years, approximately 1% of the prescriptions dispensed in the outpatient retail pharmacy settings derived from pediatricians. The use of this product appears to be almost exclusive to the adult population.

The total number of prescriptions dispensed for Xenical® comprised of new prescriptions and refill prescriptions. Therefore, the overall decline in dispensed prescriptions could have resulted from a decrease in the number of new prescriptions, refill prescriptions or both. One possible explanation for the decline could be adverse drug reactions. Adverse drug reactions that were most commonly observed in clinical trials of orlistat were related to gastrointestinal symptoms and are primarily a manifestation of the mechanism of action of the drug (e.g., oily spotting, flatus with discharge, fecal urgency, fatty/oily stool). Another possible reason for the decrease in the prescriptions dispensed maybe patients switching to other anti-obesity therapeutic agents.

Findings from this consult should be interpreted in the context of the known limitations of the databases used. NPA Plus™ data provide an estimate of the total number of prescriptions dispensed in the U.S. The data, however, do not include historical demographic information, such as age and gender. The inclusion of prescriber specialty data in this report does not include the mail order and long-term care channels. However, these channels accounted for only approximately 12% of the overall prescriptions dispensed (calculated from Tables 1 and 2).

Caremark data cannot be projected to make national level estimates of use, but its large sample size can be helpful for replicating demographic findings in IMS Health's NDTI™, where sample sizes are often small. Although the data from Caremark may not be nationally representative, they provide a useful description of prescription drug use in the U.S. for a large proportion of the population with prescription drug coverage. Estimates of the number of prescriptions dispensed nationally to pediatric populations based on the proportion dispensed to pediatric patients in the Caremark system are dependent upon the assumption that these patterns are similar across populations with and without prescription drug coverage. The accuracy of this assumption is not known at this time. In addition, reliable information for patients less than the age of 1 year is not available from this data source.

NDTI™ data provide estimates of patient demographics and indications for use of medicinal products in the U.S. Due to the sampling and data collection methodologies, the small sample

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<sup>6</sup> Governale L. Patterns of prescription weight-loss drug use. Endocrinologic and Metabolic Drugs Advisory Committee Meeting, Rockville MD. September 8, 2004. Available at: [http://www.fda.gov/ohrms/dockets/ac/04/slides/2004-4068S1\\_04\\_Governale.ppt](http://www.fda.gov/ohrms/dockets/ac/04/slides/2004-4068S1_04_Governale.ppt). Last accessed 12/9/04

size can make these data unstable, particularly when use is not prevalent in the pediatric population, as in the case of orlistat. These results should be interpreted with caution.

## **CONCLUSION**

There was an overall decrease in prescriptions dispensed for Xenical® from an estimated 1.6 million prescriptions in the 12-month period ending in September 2002 (10/01 – 9/02) to 1 million prescriptions in the 12-month period ending in September 2004 (10/03 – 9/04). This represented a 38% decrease in prescriptions dispensed for this product. Use has been decreasing in both pediatric and adult populations over the past three years. Of the total prescription claims for Xenical® paid for that time period, almost 80% were for women and only 20% for men. Overall, the use of Xenical® in the Caremark system as well as in IMS HEALTH data sources appears nearly exclusive to the adult population. The pediatric specialty represented only approximately 1% of prescriptions dispensed for this product.

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