

# A Budget Impact Analysis of Dienogest in Treating Endometriosis-Associated Pelvic Pain in Germany

Christopher Knight,<sup>1</sup> Antje Colligs,<sup>2</sup> Jens Lipinski<sup>3</sup>

<sup>1</sup> RTI Health Solutions, Manchester, United Kingdom; <sup>2</sup> Bayer-Schering Pharma, Berlin, Germany; <sup>3</sup> Bayer Vital, Leverkusen, Germany

## Introduction

- Endometriosis, characterised by the presence of endometrial-like tissue outside the uterus, is a chronic, complex, yet relatively common gynaecological disorder, affecting > 70 million females worldwide.
- Patients with endometriosis present with a variety of symptoms (e.g., chronic pelvic pain, dysmenorrhoea, and dyspareunia).
- Prevalence of endometriosis is reported as between 5% and 10% of the female population.<sup>1-4</sup>
- Dienogest is considered an advanced medical therapy for women who have not adequately responded to other medical treatment, including nonspecific pain treatment (nonsteroidal anti-inflammatory drugs) and oral contraceptives (OCs).
- The primary comparator for dienogest is the class of drugs known as gonadotropin-releasing hormone analogues (GnRH-a), which are considered the gold standard therapy for women with endometriosis-associated pelvic pain (EAPP).
- However, treatment with GnRH-a is associated with serious side effects such as decreasing bone mineral density and vasomotor symptoms; therefore, it may only be administered for a maximum of 6 months.
- A 12-month treatment with GnRH-a is only indicated with an appropriate add-back therapy (i.e., giving an additional drug to suppress the side effects).<sup>5</sup>
- Following cessation of GnRH-a treatment, women are recommended to take maintenance therapy such as an OC.<sup>6</sup>

## Objective

- To evaluate the budget impact to a health plan after introducing dienogest (2 mg) as a treatment option at the expense of GnRH-a treatment for patients with EAPP

## Methods

- The analysis was conducted from a German payer's perspective over a 5-year time horizon.
- The budget impact model (BIM) specifically considered women with EAPP, including women with newly diagnosed endometriosis and women in whom other previous medical treatment for EAPP failed.
- A recently developed cost-effectiveness (CE) model for endometriosis provided estimates of average treatment duration.
- This CE model compared different treatment pathways for women with EAPP and used a 50% improvement in pelvic pain as a definition of a treatment responder to elicit treatment duration.
- After combining epidemiologic data, market uptake assumptions from market research forecasting, current GnRH-a drug treatment costs, and average treatment duration, the BIM estimated the incremental budget impact after adopting dienogest as a treatment option at the expense of GnRH-a.
- The model assumed that during the first year 5% of patients with EAPP receive dienogest at the expense of GnRH-a. After 5 years, it was assumed that dienogest would capture 15% of the EAPP market (Table 1).

## Epidemiology

- A United Kingdom (UK) survey of women in 2001 found that 24.0% of women aged 18 to 49 years had chronic pelvic pain, excluding women with ovulation pain.<sup>7</sup>
- Zondervan and colleagues<sup>7</sup> found that only one-quarter of women with chronic pelvic pain had sought medical advice in the previous year, implying an annual prevalence in primary care of 5.7%.
- Guo and Wang,<sup>8</sup> reviewed studies of endometriosis in women with chronic pelvic pain published between 1990 and 2008 and reported an average prevalence of 44.6% (19.7%-82.1%).
- Using estimates of the female German population from the German Federal Statistical Office publications, we derived an estimate of the number of women with EAPP seeking medical treatment (Figure 1).

Figure 1. Women With EAPP

Prevalence assumptions	
Managed care payer population (100,000)	
× Percentage female (50.9%)	= 50,900
× Women aged 18-49 years (41.6%)	= 21,174
× Prevalence of chronic pelvic pain in women seeking medical intervention (5.7%)	= 1,207
× Percentage of chronic pelvic pain associated with endometriosis (44.6%)	= 539
<b>Women with EAPP seeking treatment</b>	<b>= 539</b>

## Current Market Share

- An estimate of the 2010 market share of various GnRH-a comparator treatments for EAPP was derived using the number of drug items prescribed for endometriosis from the medical index data from IMS Health for 2007 using the N80 ICD-10 code for endometriosis (baseline) (Table 1).

Table 1. Market Share (%)

Drug	2010 (Baseline)	2011	2012	2013	2014	2015
Visanne	0.0	5.0	7.0	10.0	12.0	15.0
Leuprorelin acetate	49.9	47.0	45.5	43.0	42.0	40.0
Triptorelin	2.3	2.2	2.1	2.0	1.8	1.7
Goserelin	28.2	26.2	25.8	25.4	24.6	23.7

## Treatment Costs

- The BIM considers the annual treatment costs associated with each of the comparative endometriosis treatments. The comparative treatments include all the different GnRH-a agents indicated (Table 2). Hormone replacement therapy (tibolone) and combination OCs are included because they are associated with GnRH-a treatment.
- The average annual patient cost has been estimated from the average annual treatment duration for a woman on treatment over a 2-year period, which was derived from a recently developed CE model evaluating dienogest compared with a GnRH-a.
- In any given year, the number of women receiving treatment for a given therapy will consist of women who:
  - Are new to the treatment at some point in the year
  - Continue to take the medication during the year and were on treatment in the previous year
  - Have taken the medication at some period during the year but are no longer doing so
- Using this average treatment duration assumption allows us to take a snapshot of the patient mix and provide an estimate of the annual average treatment cost for a given therapy.
- Costs include the drug, administration, and resource costs.
- The CE model results showed that women treated with dienogest were on treatment for an average of 36.8 weeks per year compared with 29.6 weeks for women treated with a GnRH-a alone or 33.2 weeks for women treated with a GnRH-a and add-back therapy.
- Women on dienogest were assumed to receive a gynaecologist consultation every 3 months, whereas women on GnRH-a received monthly gynaecologist visits while on treatment but reverted to 3 monthly general practitioner visits while receiving maintenance therapy.
- Women on a GnRH-a also received an initial outpatient visit (Table 3). For dienogest, different pricing scenarios were evaluated.

Table 2. Drug Costs

Drug	Brand	Formulation	Strength	Package Size	Cost/Package	Administration	Cost/Injection or 28 days
Goserelin	Zoladex	Injection	3.60 mg	3	€424.32	3.6 mg injection every 4 weeks	€141.44
Triptorelin	Decapeptyl	Injection	3.75 mg	3	€466.75	3.75 mg injection every 4 weeks	€155.08
Leuprorelin acetate	Enantone/Enantone-Gyn	Injection	3.75 mg	1	€127.05	3.75 mg injection every 4 weeks	€127.05
Add-back tibolone	Livial	Tablet	2.50 mg	28	€19.93	Tablet daily	€19.93
Combination OC	All 3 × 21 brands All 3 × 28 brands	Tablet	Varies	3 × 21 3 × 28	€17.37	Tablet daily	€5.79

Table 3. Resource Costs

Item	Description	Unit Cost	Source
First gynaecologist visit per 3 months	Consultation	€55.95	Using a calculation of €0.0511 per accounting point 2008. <sup>9</sup> Initial visits include (codes): lump sum for insured from 6 to 59 years (08211), consultation and examination in women who are capable of conception (01822), microscopic examination of native smear of vaginal secretion (01827), and ultrasound (33044).
Follow-up gynaecologist visit within 3 months	Consultation	€24.27	As above, but follow-up excludes 08211 and 01822.

## Results

- In the hypothetical health plan (100,000 members), ~0.54% (539) of members were estimated to be diagnosed with EAPP and receiving medical intervention.
- In the year after introduction of dienogest, the overall budget used to treat EAPP was estimated to decrease by up to 0.2%, with the budget savings estimated to increase to ~1.1% by year 5.
- The total budget for treating EAPP in the hypothetical population of 100,000 in 2010 is estimated at €558,443, with €402,034 used for drug costs and €156,409 for resource costs (Table 4).
- Extrapolating these results to the total German population estimated at 81.9 million (41.7 million women) yields an overall EAPP population of 441,000 women in Germany.
- The estimated budget for treating EAPP is €452.9 million in Germany in 2010.
- By 2015, without the introduction of dienogest, the budget is expected to increase to €552,338 due to changes in the German population.
- If dienogest is introduced, the total budget is estimated to decrease by €61,790 by 2015.
- By year 5 the introduction of dienogest could save €4.98 million.

Table 4. Budget Impact Results With Dienogest (€)

Cost	Total Population (100,000)					
	2010	2011	2012	2013	2014	2015
Drug	402,034	385,445	378,478	368,575	361,274	351,117
Resource	156,409	150,970	148,605	145,208	142,831	139,432
Total	558,443	536,415	527,083	513,783	504,105	490,549
Saving		20,943	29,111	41,179	48,572	61,790

## Conclusions

- The average patient treatment costs of dienogest are lower than for GnRH-a.
- The total budget reduction of a hypothetical health plan administrator, with a 100,000 population, is estimated at 1.1% based on dienogest capturing 15% of the GnRH-a market share (by 2015).
- Extrapolating these results to the total German population yields an overall estimated budget of €452.9 million for treating EAPP. Introducing dienogest could save €4.98 million by year 5.

## References

- Ozkan S, Murk W, Arici A. Endometriosis and infertility: epidemiology and evidence-based treatments. *Ann N Y Acad Sci* 2008;1127:92-100.
- Ozawa Y, Murakami T, Terada Y, Yaegashi N, Okamura K, Kuriyama S, et al. Management of the pain associated with endometriosis: an update of the painful problems. *Tohoku J Exp Med* 2006;210:175-88.
- Eskanazi B, Warner ML. Epidemiology of endometriosis. *Obstet Gynecol Clin North Am* 1997;24:225-58.
- Barton-Smith P, Ballard K, Kent ASH. Endometriosis: A general review and rationale for surgical therapy. *Reviews in Gynaecological and Perinatal Practice* 2006;6:168-76.
- Gambone JC, Mittman BS, Munro MG, Scialli AR, Winkler CA and the Chronic Pelvic Pain/Endometriosis Working Group. Consensus statement for the management of chronic pelvic pain and endometriosis: proceedings of an expert-panel consensus process *Fertil Steril* 2002;78:961-72.
- Kennedy S, Bergqvist A, Chapron C, D'Hooghe T, Dunselman G, Greb R, et al; on behalf of the ESHRE Special Interest Group for Endometriosis and Endometrium Guideline Development Group. ESHRE guideline for the diagnosis and treatment of endometriosis. *Hum Reprod* 2005;20:2698-704.
- Zondervan KT, Yudkin PL, Vessey MP, Jenkinson CP, Dawes MG, Barlow DH, et al. The community prevalence of chronic pelvic pain in women and associated illness behaviour. *Br J Gen Pract* 2001;51:541-7.
- Guo SW, Wang Y. The prevalence of endometriosis in women with chronic pelvic pain. *Gynecol Obstet Invest* 2006;62:121-30.
- National Association of SHI-Accredited Physicians: Doctors' Fee Scale, Version 2008. July 1, 2008.

## Contact Information

**Christopher Knight, MSc**  
Senior Health Economist  
RTI Health Solutions  
Williams House  
Manchester Science Park  
Lloyd Street North  
M15 6SE  
Manchester, United Kingdom  
Telephone: +44.161.232.3400  
Fax: +44.161.232.3409  
E-mail: cknight@rti.org



## Acknowledgement

Sponsored by Bayer Schering Pharma.

Presented at the ISPOR 12th Annual European Congress, Paris, France, October 24-27, 2009