REAL WORLD EVIDENCE

QuintilesIMS™

2013

Case Studies on Real World Evidence Impacting Payer Decisions

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INDEX – BY COUNTRY

CANADA

THERAPY AREA	BRAND	LEVER	BRIEF DESCRIPTION
CV	Spironolactone	Use	A study into the increased use of spironolactone in heart failure patients revealed higher hospitalization rates and associated in-hospital mortality which informed treatment guidelines and use of the product.
CV	Stents	Use	A prospective pragmatic registry showing that drug-eluting stents are only effective in patients at high risk for restenosis. The study informed a funding decision for 30% conversion from bare metal to drug-eluting stents for high risk patients.
Diabetes	N/A	Ongoing Access	A before and after study using micro simulation economic model informing funding for bariatric programs, and suspending funding for insulin infusion pumps.
Alzheimer's	N/A	Ongoing Access	Data collection on patient characteristics and outcomes for Alzheimer's drugs with the aim of identifying a biomarker that will show which patients will benefit from treatment.
Schizophrenia	Clozapine	Launch Access	Sandoz Canada would reimburse individuals, hospitals and government drug plans in cases where patients with treatment-resistant schizophrenia had to be taken off clozapine within six months.
CV	Endovascular abdominal aortic aneurysm repair (EVAR)	Launch Access	A prospective observation on the safety assessment of endoleak which informed a funding decision for high surgical risk patients only.
Various	Extracorporeal photopheresis	Ongoing Access	A prospective observational study which resulted in a positive funding decision for graft-versus-host disease (GvH), but an inconclusive funding decision for Sézary syndrome.
BPH	Finasteride	Launch Access	Merck-Frosst offered to reimburse provincial governments the full cost if patients prescribed finasteride subsequently required surgery for benign prostatic hyperplasia after one full year of medical therapy.

FRANCE

THERAPY AREA	BRAND	LEVER	BRIEF DESCRIPTION
Diabetes	Glitazone	Ongoing Access	A conditional reimbursement price for Actos was provided on the basis that additional results from clinical or observational studies would be provided. If the results of the studies were negative, the manufacturer would be required to pay back the difference for past overpayments and would apply for future price reductions.
CV	Statins	Use	Statin class assessment across 1 million patients which informed stricter guidelines depending on LDL level (promoting generic Pravastatine use and more targeted dosing based on patient risk status).
Schizophrenia	Risperdal	Launch Access	The full price of Risperdal funds were held in escrow until Janssen provided proof of lower hospitalization costs from a 12-month study.

GERMANY

THERAPY AREA	BRAND	LEVER	BRIEF DESCRIPTION
Oncology	Avastin	Ongoing Access	Roche agreed to provide full or partial reimbursement for patients in which the Avastin and Taxol combination exceeded a specific total dosage in a study designed to test whether the combination of both medicines could extend patient survival in mBC and mRCC.
Oncology	Remifemin	Label	A population-based case-control study revealed that Remifemin was associated with a reduction in breast cancer risk which informed the removal of risk warning from the product's label.
Diabetes	Lantus	Price	Sanofi ran a number of studies confirming Lantus' effectiveness and safety, restoring access and premium pricing in Germany.

ITALY

THERAPY AREA	BRAND	LEVER	BRIEF DESCRIPTION
Oncology	Afinitor	Launch Access	Novartis pays back 100% of the treatment cost of Afinitor in case of treatment failure after three month re-evaluation.
Oncology	Erbitux	Launch Access	Merck reimburses 50% of the cost of Erbitux in cases where patients show no response to treatment.
Oncology	Iressa	Launch Access	AZ pays back 100% of the treatment cost of Iressa in case of treatment failure after three month re-evaluation.
Oncology	Javlor	Launch Access	Pierre Fabre pays back 100% of the treatment cost of Javlor in case of treatment failure after three cycle re-evaluation.
Oncology	Revlimid	Launch Access	Celgene pays back 100% of the treatment cost in case of Revlimid failure after three cycle re-evaluation.
Oncology	Nexavar	Launch Access	Bayer rebates the cost of Nexavar in full in the case of treatment failure after a three month treatment.
Oncology	Sprycel	Launch Access	BMS provides the first month free and rebates 50% of the cost of Sprycel for non-responding patients.
Oncology	Sutent	Launch Access	Pfizer provides Sutent with a 50% discount on first two cycles of treatment.
Oncology	Tarceva	Launch Access	Roche provides Tarceva with a 50% discount on first two cycles of treatment.
Oncology	Tasigna	Launch Access	Novartis provides 100% rebate for Tasigna for non-responding patients, with the first cycle paid in full for all patients.
Oncology	Tyverb	Launch Access	GSK pays back 100% of the Tyverb treatment cost in case of failure after three month re-evaluation.
Oncology	Vectibix	Launch Access	Amgen and Dompe rebate the full cost of Vectibix therapy for non-responders after a three-cycle evaluation.
Oncology	Velcade	Launch Access	JJ pay back 50% of Velcade's treatment cost for all eligible patients during the first cycle.
Oncology	Vidaza	Launch Access	Celgene provides an 11% of discount for the first three cycles of Vidaza treatment.
Oncology	Xeloda	Launch Access	Roche reimburses the cost of Xeloda treatment in case of treatment failure in mBC.
Diabetes	Byetta	Launch Access	Payers agreed to provide provisional market access on the basis that Lilly would monitor Byetta's real life use, collect epidemiological and safety data for P&R.

ITALY (CONTINUED)

THERAPY AREA	BRAND	LEVER	BRIEF DESCRIPTION
CV	Procoralan	Launch Access	Payers agreed to provide provisional market access on the basis that Servier Italia would monitor Procoralan's real life use, collect epidemiological and safety data for P&R.
CV	Crestor	Price	AZ prevented the generic reference pricing of Crestor with a series of real world studies demonstrating that Crestor was able to get more patients to their LDL goal compared to generic simvastatin.
Diabetes	Januvia	Launch Access	Payers agreed to provide provisional market access on the basis that MSD would monitor Januvia's real life use, collect epidemiological and safety data for P&R.
Diabetes	Galvus	Launch Access	Payers agreed to provide provisional market access on the basis that Novartis would monitor Galvus' real life use, collect epidemiological and safety data for P&R reassessment.
Alzheimer's	Acetyl cholinesterase inhibitors	Launch Access	The IT NHS funded acetyl cholinesterase inhibitors such, as donepezil, on the basis of an observational study which demonstrated health gain in patients with mild to moderate Alzheimer's disease.
Wet AMD	Lucentis	Launch Access	Novartis was able to achieve reimbursement for Lucentis by agreeing to reimburse the cost of treatment for any patients who do not respond to therapy after an initial three month evaluation.
Wet AMD	Macugen	Launch Access	Pfizer was able to achieve reimbursement for Macugen by agreeing to reimburse the cost of treatment for any patients who do not respond to therapy after an initial evaluation.
Alzheimer's	Exelon	Launch Access	Novartis was able to achieve reimbursement for Exelon by agreeing to reimburse the full cost of treatment for any patient that did not achieve remission within six months.

NETHERLANDS

THERAPY AREA	BRAND	LEVER	BRIEF DESCRIPTION
CV	Generic statins	Use	The impact of statin generic substitution was evaluated among specific patient groups which informed stricter guidelines as a result of a lack of cost-effectiveness in certain patient populations.
Asthma	Xolair	Launch Access	MoH negotiated reimbursement only for patients who show improvement with Xolair. Novartis will rebate full cost of treatment for all other patients.
Stroke	Apixaban	Price	A study was set-up which supported a non-transparent negotiation on the price reduction of Apixaban by ~ 60 - 70% as payers were not convinced of the clinical value of new anti-coagulants, especially given the good track record with patient INR control in the Netherlands.

SPAIN

THERAPY AREA	BRAND	LEVER	BRIEF DESCRIPTION
Oncology	Iressa	Launch Access	Iressa was granted access in one hospital only, on the basis of outcomes collected as part of a contracting pilot project between AZ and Catalonia.
CV	Lipitor	Ongoing Access	Lipitor remained on the list of non-recommended drugs due to insufficient data on CV mortality reduction.
CV	Altace	Ongoing Access	Altace was placed on the list of recommended drugs due to improvement in hypertension lowering and reduced mortality.
COPD	Spiriva	Ongoing Access	Spiriva remained on the list of non-recommended drugs due to lack of improvement with COPD patient mortality.
MS	Sativex	Ongoing Access	Payers agreed to pay full price as long as more than 50% of patients respond to therapy.

SWEDEN

THERAPY AREA	BRAND	LEVER	BRIEF DESCRIPTION
Oncology	Zytiga	Launch Access	Access conditional on enrolment in study at launch aimed to understand whether the drug is used for the right patient.
CV	Atacand	Ongoing Access	Atacand maintained reimbursement and formulary status based on evidence showing higher survival rates and lower resource utilization costs.
CV	Drug eluting stents	Ongoing Access	The risk of death was found to be higher with drug-eluting stents, informing reimbursement, usage and global treatment guidelines.
CV	Simvastatin & atorvastatin	Use	A study on statin use found that use was low which informed recommendations to physicians to increase prescribing.
CNS	Blinded	Ongoing Access	The increase in sales of a CNS drug led the TLV to question its price and reimbursement status, but a retrospective study showed that initiating this drug reduced healthcare costs removing any restrictions on access.
Parkinson	Levodopa	Launch Access	TLV reimbursed Levodopa at a premium price and granted provisional reimbursement, conditional on the collection of RWE.
HIV	Reyataz	Launch Access	Reyataz was granted three years reimbursement to support claims of reduced GE side effects and reduced CV events through RWE studies. Rreimbursement was renewed based on improved outcomes and QoL.
Obesity	Acomplia	Launch Access	Interim reimbursement status was granted for two years until long term effectiveness and cost-effectiveness were proven using RWE studies.
Other	Nitrazepam	Use	The overall medication burden for elderly patients was considered too high which informed an overall reduction in prescriptions from real world studies.
Narcolepsy	Xyrem	Use	Paediatric patients developed narcolepsy in response to the swine flu vaccine. While Xyrem did not have a paediatric label, Swedish authorities agreed to recommend its use in conjunction with the collection of RWE.

UK

THERAPY AREA	BRAND	LEVER	BRIEF DESCRIPTION
Oncology	Iressa	Launch Access	AZ agreed to a cost-sharing scheme based on outcomes collection due to Iressa's high cost and unproven advantage over platinum therapy.
Oncology	Navelbine	Use	Navelbine use reduced outpatient visit time by 90% leading to preference for oral over IV formulations.
CV	Lipitor	Ongoing Access	Pfizer refunds the NHS if atorvastatin fails to reduce LDL levels to pre-specified targets.
CV	Clopidogrel	Use	A study on the early discontinuation of oral anti-platelet therapies informed clinical guidelines on the appropriate duration of treatment.
COPD	Daxas	Label	Suicidal behavior was reported in patients without a history of depression, informing a label safety warning.
Asthma	ICS/LABAS	Use	Off-label prescribing was shown to be an economically wasteful practice and informed greater adherence to clinical guidelines.
Pain	Lyrica	Launch Access	Lyrica was not included in hospital formularies due to higher rate of side effects, frequency of outpatient visits, and daily cost of therapy.
Wet AMD	Avastin	Use	Avastin was used off-label to treat wet AMD in the real-world, leading to even greater numbers of ophthalmologists using it in the place of Lucentis.
RA	Cimzia	Use	Cimzia's lower response rate informed its removal from hospital formularies.
Cystitis	Cystistat	Launch Access	Cystistat was granted conditional access, even though it did not have compelling evidence, pending PRO collection by physicians who pushed for its use.
Dermatology	Emollients	Ongoing Access	A PCT switched to single company for all emollient needs based on satisfaction data from 100 patients.
RA	Enbrel	Use	Enbrel was preferred over Humira for patients at higher risk of TB after real-life study informed appropriate usage of RA biologics in defining subpopulations.
LEMS	Firdapse	Ongoing Access	PCTs refused access to the first licensed treatment for LEMS because of real world use of an unlicensed therapy.
MS	Interferon beta or glatiramer	Launch Access	Coverage with evidence development, but scheme failed despite data collection.
Dupuytren's contracture	Acetate	Use	Funding decision for Xiapex was based on a study investigating a reduction in surgical intervention.

USA

THERAPY AREA	BRAND	LEVER	BRIEF DESCRIPTION
Oncology	N/A	Ongoing Access	Pay for performance pilots in oncology where the manufacturer covers the cost of treatment in case of no response as defined by improvements in progression free survival.
Oncology	Oncotype DX test	Launch Access	United Healthcare reimbursed Genomic Health's Oncotype Dx test at the list price following a study where clinical effectiveness was verified in breast cancer patients for 18 months.
Oncology	Tysabri	Label	Tysabri was initially withdrawn from market due to serious adverse events but was then re-introduced under CED as real world studies contributed to demonstrating that benefits outweigh risks.
Osteoporosis	Actonel	Ongoing Access	The cost of non-spinal bone fractures were reimbursed, delaying generic competition, and helping Actonel in achieving preferred formulary position compared to competitor Boniva.
Osteoporosis	Boniva	Ongoing Access	Boniva moved to a non-preferred tier after it was ranked lowest on WellPoint's real world analysis of 26,000 members.
CV	Effient	Ongoing Access	Medco study demonstrated that Effient is not cost-effective relative to Plavix, which informed a non-coverage decision on the Medco Medicare closed formulary.
Diabetes	Januvia/Janumet	Ongoing Access	Cigna lowered patient co-pay for Januvia and Janumet after Merck fixed the cost and offered discounts for patient adherence to drug regimen and control of blood pressure.
CV	Lipitor	Use	A national claims database study showed superior outcomes for Lipitor versus generics in non-CVD patients, broadening the target population of Lipitor.
GI	Nexium	Ongoing Access	Nexium was withdrawn from United Healthcare's formulary after internal retrospective study showed Nexium was not cost-effective.
CV	Plavix	Label	Medco study on Warfarin led to an FDA labeling change providing dose recommendations based on genetic test results.
CV	PPI/Plavix	Label	FDA black box warning on Plavix with concomitant PPI use post-Medco study.
Depression	Prozac	Use	Group Health conducted an RWE study measuring outcomes where Prozac was found to be no more expensive than treatment with generic desipramine, imipramine when total treatment cost was considered.
Erectile Dysfunction	Viagra	Ongoing Access	Viagra regained formulary status after six years, replacing Bayer's Levitra and Staxyn after sharing cost effectiveness data.

USA (CONTINUED)

THERAPY AREA	BRAND	LEVER	BRIEF DESCRIPTION
MS	Rebif	Ongoing Access	Merck agreed to provide rebate payments for MS drug, Rebif, tied to the number of hospital visits as a result of relapses with Cigna and Prime Therapeutics.
RA	Remicade	Ongoing Access	Prior-authorization for infliximab was removed based on compliance and outcomes demonstration, relative to the injectables Humira and Enbrel, in a study conducted by BCBS (other RA biologics continued to have a PA).
Other	N/A	Use	Analysis of NIS hospital database facilitated product entry and use in an effort to understand budget impact of rapid screening and prophylaxis for S.aureus colonization.

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