

Cost-Minimization Analysis of Medications Used in the Management of End-stage Renal Disease

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ABSTRACT

Aim/Background: Several branded pharmaceuticals and generic medicines are available in the market for the management of End-Stage Renal Disease (ESRD) as a supportive care, and clinicians are unaware of the cost minimization and cost consequences aspects of these medications. Thus, this study aimed to compare the prices of branded versus generic medicines for ESRD treatment and to present the cost savings with a generic alternative. **Materials and Methods:** A prospective observational study was conducted among ESRD patients from three different tertiary care teaching hospitals in South India. The cost of branded pharmaceuticals were determined using the most recent current index of medical specialties, while the prices of generic medicines were accessed using the Pradhan Mantri Bhartiya Jan Aushadhi Pariyojana scheme, 2022. **Results:** The data were collected from 385 patients with ESRD. All Jan Aushadhi generic medicines were less expensive when compared to the branded medicines. The cost of ESRD medicines accessible in India varies greatly. The greatest difference in percentage cost savings were noted with amlodipine 5 mg tab (93.03%), voglibose 0.2mg/tab (88.10%), calcium carbonate + Vitamin D₃ supplements 500 mg tab (80.27%), torsemide 10 mg tab (78.01%), and hematopoietic agent, erythropoietin 2000 U/inj (75.38%). **Conclusion:** The haematopoietic medicines and antidiabetic insulin injections were the most expensive medicines among the study population. Our research indicates that replacing the generic medicines with the branded medicines could help in reducing the cost burden. Healthcare professionals may consider prescribing generic medicines for cost-savings.

Keywords: Pharmacoeconomics, Cost minimization, End stage renal disease, Antibiotics, Insulin, Jan Aushadhi.

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INTRODUCTION

End-Stage Renal Disease (ESRD) is a severe medical condition which contribute to the serious health consequences and financial burden. As per the recent statistics, the global prevalence of Chronic Kidney Disease (CKD) is estimated to be 13.4% (11.7-15.1%) with 4.902 to 7.083 million people required Renal Replacement Therapy (RRT) with ESRD.¹ In India, 152 individuals in a million population have ESRD and the most frequent cause of ESRD is diabetic renal disease.² The global variation in prevalence and incidence of ESRD is based on each nation's specific genetic, environmental, lifestyle, and sociodemographic behaviors.³ Though there are many RRT are available, the choice

and adherence are based on the patient's financial background and affordability.⁴

The term Pharmacoeconomics (PE) defined as "the studies that evaluates the behavior of individuals, firms, and markets relevant to the use of pharmaceutical products, services, and programs, and which majorly focuses on the costs (inputs) and consequences (outcomes) of that use."^{5,6} The PE evaluations includes the Cost Minimization Analysis (CMA), Cost Effectiveness Analysis (CEA), Cost Utility Analysis (CUA), and Cost Benefit Analyses (CBA). CMA is an excellent PE method for assessing the drug costs and highlights the least costly drug or therapeutic modality between the similarly efficacious drugs or procedures.⁷

It is well documented that, ESRD being advanced stage of CKD, burden the patient and patient relatives.^{8,9} The higher costs of hemodialysis and the associated medicines itself forces the patient and patient party to non-adhere the treatment pattern in many ways like, cut down on the number of dialysis procedures



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prescribed, not procuring the medicines as prescribed or incomplete duration of the treatment. There was a significant association between the ESRD and non-adherence of therapy. Also, the evidences indicate the influence of poor financial background in discontinuation or non-adherence of treatment.^{10,11} The cost of therapy is one of the most important components of medical management and price of medicines is the most significant cost that the patients or patient party must endure it. The trademark or branded drug prescribing nature of the physician burdens the patients and may lead to the patient non-compliance or non-adherence.^{10,12} Hence, CMA are very much important to give a clear insight to reduce the economic burden, enhance the treatment adherence, and better patient outcomes. Moreover, the CMA compares and measures input costs under the assumption that the outcome is equivalent between two alternatives which are clinically equivalent.^{13,14}

Table 1: Socio-demographic and medical outline of hemodialysis sufferers at tertiary care Hospital (n= 385).

Parameters	Total number and percentage (n=385)
Gender	
Male	283 (73.50%)
Female	102 (26.49%)
Family annual gross income	
Less than 1 lakh	136 (35.32)
1-5 lakh	168 (43.63)
5-10 lakh	63 (16.36)
More than 10 lakhs	18 (4.67%)
Residence area	
Urban	147 (38.18)
Rural	238 (61.81)
Social History	
Smoking	49 (12.72)
Alcohol	32 (8.31)
None	304 (78.96)
Number of Hemodialysis (sessions / week)	
One / week	14 (3.63)
Two/ week	301 (78.18)
Three /week	70 (18.18)
Total number of medications	
<5	36 (9.35)
5 to 10	251 (65.19)
11 to 15	90 (23.37)
16 to 20	8 (2.07)

Pharmaceuticals used as supplementary systematic therapy are manufactured by numerous drug companies and sold under variety of brands at high prices that are unaffordable to the patients, particularly in developing countries like India. Whereas the generic medicines are accessible in the Indian market at a lower cost which are having the equal efficacy and safety.⁷ To address these issues of accessibility of medicine to a huge proportion of the community, the government of India has launched many initiatives through different programs and schemes intended to increase public awareness of generic medicines. One such initiative is Jan Aushadhi.

Many supplementary medications for hemodialysis at ESRD are now available at low prices as generic medicines under the Pradhan Mantri Bhartiya Jan Aushadhi Pariyojana (PMBJP) scheme, which are marketed and made public through the Jan Aushadhi Kendra drugstores to offer various generic medicines to the populace.¹⁵ However, no studies have been conducted to provide information on the cost differences for each therapeutic dose, for a given period, as well as operating costs when using generic medicines for ESRD patients. Hence, we used CMA method to analyze the proportion of price fluctuation as well as evaluated price reductions through prescribing the generic alternative of the branded medicines in the overall length of therapeutic interventions among the patients with ESRD which will help to give a clear picture of the current scenario and assist to make further policies in future.

MATERIALS AND METHODS

Ethical approval

The ethical clearance to conduct this research is obtained from the respective institutional ethics committees of the study sites included. The study is conducted in accordance with the terms of the 1995 Helsinki Declaration (as revised in Edinburgh 2000), ensuring the confidentiality of patient data. Also, the study protocol is registered in Clinical Trial Registration-India (CTRI) with a registration number CTRI/2019/08/020874.

Study setting and design

This research was designed and conducted as a prospective CMA among the ESRD patients at three prominent tertiary care teaching hospitals in Karnataka, India, during the six months (November 2021 to April 2022).

Study participants

The non-probability convenience sampling method was used for the selection of patients. The ESRD patients who are undergoing the hemodialysis with an age of 18 or above were considered in this study. The AKI or CKD patients without hemodialysis or with peritoneal dialysis, pregnant woman, and patients with hemodialysis for less than three months were excluded from the

study. Patients who were undergoing therapy on the day of the visit and who refused to give permission were also not included in the study. Participation in the research was voluntary and written consent was obtained from patients who accepted to be a part of the research.

Data collection

The drug utilization pattern of various medications was collected from the patient's medication chart. The information such as name of the brand, generic name, dose, route of administration, frequency and duration of treatment were noted on a well-defined data collection form. The data was classified in accordance with the category of medication.

Cost data

The online CIMS was utilized to obtain price information for each branded medicine, and the generic version available in the Indian market was obtained through the Jan Aushadhi scheme portal. The variation in the percentage of cost and the cost-saving potential for haemodialysis regimens was then calculated by incorporating the available generic drug and forecasting it using the standard formula. The medicine prices were expressed in Indian Rupees (INR).

Cost-minimization analysis

All the drug prices were mentioned in Indian rupees, and each drug's price was compared to the equivalent generic version. The cost difference between the branded drug to the generic drug was calculated, and consecutive data was entered into the excel sheet. To calculate the overall cost of therapy, the cost of each drug was determined. The individual medicine cost was compared, and the calculated amount was denoted as percentage variation. Cost savings was presented by drug therapeutic category wise. The percentage cost variation was calculated using the formula given by the previous literature.^{7,14}

$$\text{Percentage cost savings} = \frac{\text{Difference in the cost between branded and generic drugs}}{\text{Cost of branded drug}} \times 100$$

Statistical analysis

The information was entered into Microsoft Excel (version 2016) and presented in tabular format. A descriptive statistics were used to compute the demographic data and presented in frequency in percentage. All the cost minimization results were presented in percentage.

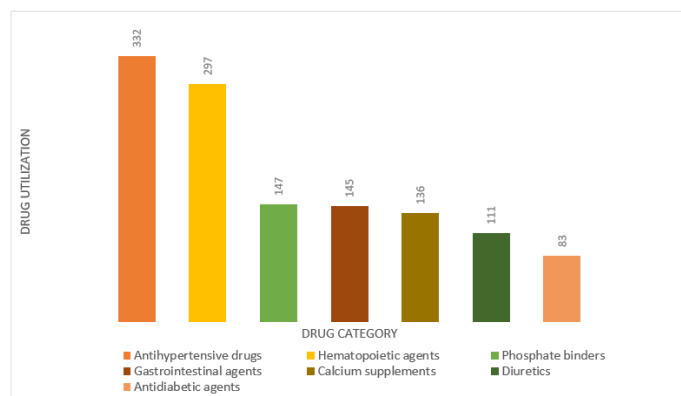


Figure 1: Drug utilization pattern among the ESRD patients.

RESULTS

Demographics of the included patients

A total of 385 patients with a mean age of 53.79 (13.61) years undergoing ESRD treatment at three different study sites were enrolled. The majority (73.50%; $n=283$) of the population were male and remaining 26.49% ($n=102$) were female. The major proportion of the included participants were receiving dialysis at the general dialysis units (87.27%; $n=336$), followed by the isolation room (6.49%; $n=25$), and special dialysis units (6.23%; $n=24$). The demographic characteristics of patients is provided in Table 1.

Drug utilization pattern

Out of 385 patients included, 332 (86.23%) patients used antihypertensive drugs, 297 (77.14%) used hematopoietic agents, 147 (38.18%) used phosphate binders, 145 (37.66%) used gastrointestinal agents, 136 (35.32%) used calcium supplements, 111 (28.83%) used diuretics, and 83 (21.55%) used antidiabetic agents. The drug utilization pattern among the participants is given in Figure 1.

Cost-minimization analysis

The monthly expenditure may be saved if hemodialysis patients used generic medicines. Antihypertensive (HTN) agents such as S (-) Amlodipine 5 mg/tab (93.03%), Cilnidipine 20 mg/tab (87.98%), Amlodipine 10 mg/tab (81.81%), Prazosin HCl 2.5 mg/tab (74.52%), Carvedilol 6.25 mg/tab (89.06%), Metoprolol 50 mg/tab (77.32%), Atenolol 50 mg/tab (79%), Nebivolol 5 mg/tab (70.67%), Telmisartan 40 mg/tab (83.37%), Enalapril 5mg/tab (86.11%), and Labetalol (74.70%) are depicted in Table 2. HTN medications have the lowest chance of saving the cost for HD patients e.g., Clonidine 100 mcg/tab (34.30%), Nifedipine 10 mg tab (16.66%). Hematopoietic agents Erythropoietin 4,000 U/inj (66.21%) and 2000 U/inj (75.41%). Cresp (Darbepoetin alfa) and Venofer (Iron Sucrose) injections are not provided under the Jan Aushadhi scheme. Phosphate binders, such as calcium acetate 667 mg/tab, can save 33.80% of the amount. The

Table 2: Cost-minimization analysis for antihypertensive, hematopoietic, and phosphate binders.

Brand name (Generic name)	Dose	Monthly consumption	Unit cost of branded drugs (In rupees INR)	Monthly cost of branded drugs (In rupees INR)	Unit cost of generic drugs (In rupees INR)	Monthly cost of generic drugs (In rupees INR)	Monthly cost minimization (Difference between branded and generic drugs) (In rupees INR)	Percentage cost Savings
Anti-hypertensives								
Arkamin (Clonidine)	100 mcg/ tab	60	1.37	82.2	0.9	54	28.2	34.30
Nicardia (Nifedipine)	5 mg/cap	90	1.6	144	-	-	-	-
	10 mg/cap		0.96	86.4	0.8	72	14.4	16.66
Cilacar (Cilnidipine)	5 mg/tab	60	5.95	357	1	60	297	83.19
	10 mg /tab		9.88	592.8	1.5	90	502.8	84.81
	20 mg/tab		14.98	898.8	1.8	108	790.8	87.98
Amlodac (Amlodipine)	5 mg/tab	60	2.74	164.4	0.5	30	134.4	81.75
	10 mg/tab		5.5	330	1	60	270	81.81
Prazopress XL (Prazosin HCl)	2.5 mg/tab	60	7.85	471	2	120	351	74.52
Cardivas (Carvedilol)	3.125 mg/ tab	60	4	240	0.7	42	198	82.5
	6.25 mg/tab		6.4	384	0.7	42	342	89.06
Metolar (Metoprolol)	25 mg/tab	60	2.4	144	0.6	36	108	75
	50 mg/tab		3.97	238.2	0.9	54	184.2	77.32
Asomex (S (-) Amlodipine)	2.5 mg/Tab	60	4.59	275.4	1.1	66	209.4	76.03
	5 mg/tab		9.47	568.2	0.66	39.6	528.6	93.03
Aten (Atenolol)	25 mg/tab	60	1.99	119.4	0.42	25.2	94.2	78.89
	50 mg/tab		2	120	0.42	25.2	94.8	79
Nebicard (Nebivolol)	2.5 mg/tab	60	8.48	508.8	2.6	156	352.8	69.33
	5 mg/tab		13.64	818.4	4	240	578.4	70.67
Telma (Telmisartan)	20 mg/tab	60	3.99	239.4	1	60	179.4	74.93
	40 mg/tab		7.22	433.2	1.2	72	361.2	83.37
	80 mg/tab		11	660	2.2	132	528	80
Envas (Enalapril)	5 mg/tab	60	3.61	216.6	0.5	30	186.6	86.14
Lobet (Labetalol)	100 mg/tab	60	17.79	1067.4	4.5	270	797.4	74.70
Haematopoietic agents								
Eryprosafe (Erythropoietin)	4,000 U/inj	4	879.2	3516.8	297	1188	2328.8	66.21
	2,000 U/inj	8	853.32	6,826	210	1680	5,146	75.38
Cresp (Darbeoetin alfa)	60 mcg/inj	4	4900	19600	-	-	-	-
Venofer (Iron (Sucrose)	100 mg/inj	8	360	2880	-	-	-	-

Brand name (Generic name)	Dose	Monthly consumption	Unit cost of branded drugs (In rupees INR)	Monthly cost of branded drugs (In rupees INR)	Unit cost of generic drugs (In rupees INR)	Monthly cost of generic drugs (In rupees INR)	Monthly cost minimization (Difference between branded and generic drugs) (In rupees INR)	Percentage cost Savings
Phosphate binders								
Phostat (Calcium acetate)	667 mg/tab	90	4.23	380.7	2.8	252	128.7	33.80
Revlamer (Sevelamer carbonate)	400 mg/tab	90	8.6	774	-	-	-	-
Fosbait (Lanthanum carbonate)	250mg/tab	90	13.61	1,224.9	-	-	-	-
	500 mg/tab		29.68	2,671.2	-	-	-	-
Dynulta (Sucroferric oxyhydroxide)	2500mg/tab	90	-	-	-	-	-	-

phosphate binders that are not available for haemodialysis under the Jan Aushadhi scheme, are Revlamer (Sevelamer carbonate), Fosbait (Lanthanum carbonate), and Dynulta (Sucroferric Oxyhydroxide). Haematopoietic medicines and phosphate binders are very expensive for HD patients.

DISCUSSION

Indian population suffers numerous issues when it comes to paying for medicines. This is due to their lack of knowledge about various health regulations and government schemes, as well as the fact that they must pay the bills out of their own pockets.¹⁶ Health care professionals should be aware to offer them the best drug with least price. The cost analysis study become particularly crucial to provide better medical care to more patients at a lower cost while maintaining efficacy and safety to the greatest extent possible.¹⁴ The economic situation in India, particularly in hemodialysis treatment, makes it difficult to pay for 80-90% of the treatment costs.¹⁷ In this case, the findings of our study will be useful in the selection of low-cost drugs. The results presented in this study provide more clarity to understand the individual drug users based on their therapy. As a result of this, the overall cost savings can be demonstrated in the study concerned with the field category of each drug. The outlay opportunities from branded drugs to generic drugs, which are commonly used in haemodialysis therapy could be beneficial to the patients to reduce the cost burden especially in a country like India. The PMBJP scheme in India has played a significant role in lowering miscellaneous costs and offering better medicines at a reasonable cost. Moreover, this plan offers various economic benefits, such as medication price control, tax reductions, and the regular updating of critical drug information.¹⁸ As per a

medication audit, about 80% of all pharmaceuticals in India are promoted like trademarked compounds, which are costly than their non-branded generic counterparts.¹⁹ Nevertheless, different investigations have demonstrated that unbranded medications are equally efficacious as trademarked pharmaceuticals as well as meet the quality criteria of the Indian Pharmacopoeia.²⁰ Furthermore, comparative studies have confirmed that substituting non-branded medications can result in a 15% reduction in overall medication costs.²¹ Our findings indicate that pricing of various drugs used during the ESRD management vary widely in Indian healthcare market. The medicines with the highest cost-benefit ratios in INR per month are antihypertensive agents, such as labetalol (100mg/tab), cilnidipine (20 mg/tab), nebivolol (5 mg/tab), S (-) amlodipine, and telmisartan (80 mg/tab). The haematopoietic agents such as erythropoietin (2,000 U/inj), phosphate binders are calcium acetate (667 mg/tab), gastrointestinal agents, pantoprazole + domperidone (40 mg cap), rabeprazole (20 mg/tab), and esomeprazole (40 mg/tab). The calcium supplements like calcium carbonate + Vitamin D₃ (500 mg/tab), and diuretics torsemide (10 mg/tab). Antidiabetic agents including Insulin human (recombinant; 40 IU/inj), Insulin human (soluble; 40IU/inj), vildagliptin (50 mg/tab) and voglibose (0.3 mg/tab). The medicines with the lowest cost-benefit ratios in INR per month are antihypertensive drugs such as amlodipine (5mg/tab), atenolol (25 mg/tab), metoprolol (25 mg/tab), clonidine (100 mcg/tab), and nifedipine (10 mg/cap). The haematopoietic agents like erythropoietin (2,000 U/inj). The gastrointestinal agents are omeprazole 20 mg/cap, ranitidine 150 mg/tab, and famotidine 20 mg/tab. Calcium supplements like calcium with Vitamins (0.25 mcg/tab), and diuretics frusemide (40 mg/tab). Also, the antidiabetic agents like glipizide (5 mg/tab), metformin (500 mg/

Table 3: Cost-minimization analysis for gastrointestinal agents, calcium supplements, diuretics, and antidiabetic agents.

Brand name (Generic name)	Dose	Monthly consumption	Unit cost of branded drugs (In rupees INR)	Monthly cost of branded drugs (In rupees INR)	Unit cost of generic drugs (In rupees INR)	Monthly cost of generic drugs (In rupees INR)	Monthly cost minimization (Difference between branded and generic drugs) (In rupees INR)	Percentage cost Savings
Gastrointestinal agents								
Pan D (Pantoprazole + Domperidone)	40 mg/ cap	60	11.86	711.6	2.2	132	579.6	81.45
Omez (Omeprazole)	20 mg/ cap	60	3.68	220.8	0.9	54	166.8	75.54
Nexpro (Esomeprazole)	20 mg / tab	60	5.12	307.2	1	60	247.2	80.46
	40 mg/ tab		9.10	546	1.9	114	432	79.12
Rantac (Ranitidine)	150 mg/ tab	60	1.22	73.2	0.5	30	43.2	59.01
Rabicip (Rabeprazole)	20 mg/ tab	60	9.75	585	0.8	48	537	91.79
Acilo (Famotidine)	20 mg/ tab	60	0.32	19.2	0.21	12.6	6.6	34.37
	40 mg/ tab		0.56	33.6	0.28	16.8	16.8	50
Calcium supplements								
Shelcal (Calcium carbonate + Vitamin D ₃)	500 mg/ tab	60	6.59	395.4	1.3	78	317.4	80.27
Calcit (Calcium with Vitamins)	0.25 mcg/tab	30	6.4	192	1.3	39	153	79.68
Diuretics								
Frusenex (Frusemide)	40 mg/ tab	60	0.52	31.2	0.5	30	1.2	3.84
Dytor (Torsemide)	10 mg/ tab	60	5.14	308.4	1.13	67.8	240.6	78.01
Antidiabetic agents								
Ten 20 (Teneligliptin)	20 mg/ tab	60	11.95	717	5	300	417	58.15
Reclide – XR (Gliclazide)	60 mg/ tab	60	11.75	705	4	240	465	65.95
Volibo (Voglibose)	0.2 mg/ tab	60	9.25	555	1.1	66	489	88.10
	0.3 mg/ tab	60	12.5	750	1.4	84	666	88.8
Obimet (Metformin)	500 mg/ tab	60	1.64	98.4	0.6	36	62.4	63.41
Galvus (Vildagliptin)	50 mg/ tab	60	19.93	1,195.8	4	240	955.8	79.92

Brand name (Generic name)	Dose	Monthly consumption	Unit cost of branded drugs (In rupees INR)	Monthly cost of branded drugs (In rupees INR)	Unit cost of generic drugs (In rupees INR)	Monthly cost of generic drugs (In rupees INR)	Monthly cost minimization (Difference between branded and generic drugs) (In rupees INR)	Percentage cost Savings
Glynase (Glipizide)	5 mg/tab	60	0.61	36.6	0.5	30	6.6	18.03
Human actrapid (Insulin human, Recombinant)	40 IU/inj	45	154.66	6,959.7	80	3600	3359.7	48.28
Human mixtard (Insulin human, soluble)	40 IU/inj	45	158.42	7,128.9	90	4050	3078.9	43.18

tab), teneligliptin (20 mg/tab), and gliclazide (60 mg/tab) are depicted in Table 3. Interestingly, Erythropoiesis-Stimulating Agents (ESAs) have a significant impact on the health of patients suffering from renal anemia. ESAs are extremely expensive, and access to them is likely to be limited.

Results of the study clearly indicate that switching from branded medicines to generic equivalents can be an important strategy to reduce the economic burden in a condition like ESRD and in a country like India, where health is completely an out-of-pocket expenditure. Similarly, other CMA on medications like chemotherapeutic agents and proton pump inhibitors from South Indian states also indicates a cost savings from generic alternative replacements. Venkataraman R *et al.*, indicated a potential cost saving of INR 41582 by replacing the branded medicines with its generic alternatives in proton pump inhibitors. Also, they observed a percentage cost variation from 135% to 490% with esomeprazole and pantoprazole, respectively.¹⁴ Similarly, the study by Kashyap *et al.*, recorded that, cyclophosphamide and 5-Fluorouracil observed to have a 25% to 606.11% cost variation, respectively. A lowest variation was observed with cyclophosphamide (71.42%-114.28%) and highest with gemcitabine (373.68%-990.78%) between its different brands compared with the generic alternatives.⁷ Our results were also in line with the findings of the previous evidences and an extensive cost minimization and other pharmacoeconomic evaluations are needed to reduce the cost burden among the patients especially in a developing country like India. These evidences could help in the development of policy making by the respective authorities and stress the need to be implemented in the healthcare system of India.

CONCLUSION

The study findings indicate that substituting the branded medication with a generic alternatives could help the patients to reduce the economic burden, especially in patients with

ESRD. This will help in a better patient compliance, treatment adherence and treatment outcomes. Healthcare practitioner may adopt prescribing the generic alternatives with least price without compromising the efficacy of the drug for the benefit of the ESRD patients.

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CONFLICT OF INTEREST

The authors declare that there is no conflict of interest.

ABBREVIATIONS

CMA: Cost minimization analysis; **PMBI:** Pharmaceuticals and Medical Devices Bureau of India; **PMBJP:** Pradhan Mantri Bhartiya Jan Aushadhi Pariyojana; **ESRD:** End stage renal disease; **HD:** Haemodialysis; **ISPOR:** International Society for Pharmacoeconomics and outcomes Research. **OOPEs:** Out-of-pocket expenditures; **API:** Active Pharmaceutical Ingredient; **INN:** International Nonproprietary Names; **CBA:** Cost Benefit analysis; **CEA:** Cost effectiveness analysis; **CUA:** Cost utility analysis; **CCA:** Cost consequence analysis; **COI:** Cost of Illness.

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