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Supplementary Table 1. Impact inventory for cost-effectiveness analysis (CEA)^a

Sector	Type of Impact	Included in this reference case analysis		Notes on sources of evidence
		Health Care Sector	Societal	
Formal health care sector				The within-trial CEA used the observed trial data and the cost assumptions provided in eTables 3-5. The lifetime CEA used the modified Sheffield T1D model (Thokala et al. 2013) ¹ and cost, health-utility, and other input parameters provided in eTables 6-8.
Health	Health outcomes (effects)			
	Utility	Yes	Yes	
	HbA1c	Yes	Yes	
	Daily rate of NSHEs	Yes	Yes	
	BMI	Yes	Yes	
	# of patients having severe hyper events	Yes	Yes	
	# of patients having severe hypo events	Yes	Yes	
	Medical costs			
	Direct trial personnel costs	Yes	Yes	
	Medical care costs including healthcare services	Yes	Yes	
test strip use	Yes	Yes		
insulin	Yes	Yes		
Device (CGM) costs	Yes	Yes		
Informal health care sector				
Health	Self-management costs	NA	Yes	
Non-health care sectors				
Productivity	Costs of unpaid lost productivity due to illness if employed	NA	Yes	
	Costs of underperformance due to illness if employed	NA	Yes	

^a The impact inventory table was based on the recommendations of the Second Panel on Cost-Effectiveness in Health and Medicine.²

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Supplementary Table 2. Reporting checklist for cost-effectiveness analysis^a

Element	Journal Article	Technical Appendix
INTRODUCTION		
Background and objectives	Yes	
RESEARCH DESIGN AND METHODS		
Study design	Yes	
Target populations and subgroups	Yes	
Setting and location	Yes	
Study perspective	Yes	
Comparator	Yes	
Time horizon	Yes	
Discount rate	Yes	
Type of analysis	Yes	
Choice of health outcomes	Yes	
Measurement of effectiveness	Yes	
Measurement and valuation of preference-based outcomes	Yes	Yes
Estimating resources and costs	Yes	Yes
Currency, price date, and conversion	Yes	Yes
Choice of model	Yes	
Assumptions		Yes
Analytic methods	Yes	
RESULTS		
Study parameters	Yes	Yes
Incremental costs and outcomes	Yes	Yes
Characterizing uncertainty	Yes	Yes
Characterizing heterogeneity	Yes	Yes
DISCUSSION		
Study findings, limitations, generalizability, and current knowledge	Yes	
OTHER		
Source of funding	Yes	
Conflicts of interest	Yes	

^a The reporting checklist was based on the recommendations of the Consolidated Health Economic Reporting Standards (CHEERS) statement.³

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Supplementary Table 3. Within-trial cost assumptions

Within Trial Cost Assumptions		
Item	Unit Cost (2015 USD)^a	Source
Direct CGM Personnel Costs: Time of investigators/coordinators devoted to training/counseling patients on both RT-CGM and usual care		
Primary care provider	\$94.43/hour	Bureau of Labor Statistics 2016 ⁴
Advanced nurse practitioner	\$47.21/hour	Bureau of Labor Statistics 2016
Registered nurse	\$32.45/hour	Bureau of Labor Statistics 2016
Diabetes educator	\$37.35/hour	Bureau of Labor Statistics 2016
Other provider	\$35.92/hour	Bureau of Labor Statistics 2016
Direct Medical Care Costs		
Average daily insulin use over 6 months	\$0.15/unit of insulin	Redbook 2016
Average daily fingerstick use over 6 months	\$0.06/lancet \$1.02/test strip	Redbook 2016
Event Complication Costs		
Outpatient diabetes care: primary care provider	\$94.43/event	Bureau of Labor Statistics 2016
After-hours urgent care clinic visit	\$180.23/event	Mehrotra et al 2005 ⁵
911 call	\$0.86 surcharge/month	National Association of Emergency Numbers ⁶
Outpatient care: emergency department	\$476.06/event	Taubman et al 2014 ⁷
Ambulance use	\$506.36/event	U.S. GAO Report to Congressional Committees, 2012 ⁸
Hospitalization (all causes)	\$10,443.06/event	Healthcare Costs and Utilization Project ⁹
Hospitalization due to hypoglycemic episode	\$16,806.70/event	Ward et al 2014 ¹⁰
Hospitalization due to hyperglycemic episode	\$15,657.00/event	St Charles et al 2009 ¹¹
Hospitalization for other diabetic event	\$10,107.70/event	Healthcare Costs and Utilization Project
Indirect Costs		
Days of work missed due to diabetes--patient	Age and sex specific median hourly wage	Bureau of Labor Statistics 2016
Days of underperformance at work with productivity <50%	Age and sex specific median hourly wage	Bureau of Labor Statistics 2016

^a The annual inflation rate for a given year is the percent change from the previous year. Inflation rates were obtained from the Personal Consumption Expenditures: Chain-type Price Index (PCEPI), downloaded through the link: <https://fred.stlouisfed.org/series/PCEPI>. As an example, to convert a price expressed in 2010 dollars to 2015 dollars, one would use the following equation ((PCEPI(2015)/PCEPI(2010) x Price (2010)= Price (2015)).

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Supplementary Table 4. Itemized blood glucose monitoring annual cost assumptions^e

Component	Control (self-monitoring)	CGM			
		Dexcom G4 (base case)	Dexcom G4 (real-world use)	Dexcom G5	Dexcom G5 (real-world use)
Test strips ^a	\$1,629.98	\$1,330.84	\$1,330.84	\$1,104.52	\$1,104.52
CGM sensor ^b	-	\$4,066	\$2,283.44	\$4,066	\$2,283.44
CGM receiver ^c	-	\$476.63	\$317.75	\$482.17	\$482.17
				(\$241.085)	(\$241.085)
CGM transmitter ^d	-	\$1,004.96	\$669.97	\$1,014.44	\$1,014.44
Total	\$1,629.98	\$6,878.43	\$4,602.00	\$6,789.88	\$5,125.65
				(\$6,548.79)	(\$4,884.57)

- ^a Test strip cost was calculated assuming a cost of \$1.08 per test strip (see Supplementary eTable 3). For Dexcom CGM G5, the cost was calculated assuming 2.8 daily tests stated in the REPLACE-BG trial¹².
- ^b Dexcom sensors should be replaced every 7 days per label indication and cost \$78.20 each. In real-world use, patients typically use one sensor per 10 days without comprising safety¹³ and wear it 80% of the time.
- ^c Dexcom CGM receivers have a warranty of 1 year. Numbers in parentheses indicate the cost associated with year 2+ of purchasing a CGM package, assuming 50% of patients would use their smart phone as the CGM receiver.
- ^d Dexcom G4 transmitter costs \$502.48 and has a warranty of 6 months, but typically lasts 9 months. Dexcom G5 transmitter costs \$253.60, has a warranty of 3 months, and shut off at 3 months.
- ^e The prices of CGM components were the estimated average allowable prices in the U.S. marketplace and were provided by the Dexcom Pricing Department.

Supplementary Table 5. Clinical input parameters for the long-term cost-effectiveness model

Cohort baseline characteristics	Mean (SD)			
Gender-female (%)	44%			
Race-white (%)	94%			
Smokes (%)	19%			
Age	47.59 (13.04)			
T1D duration (year)	20.75 (13.60)			
HbA1c	8.63 (0.64)			
Systolic blood pressure	118.45 (16.90)			
High-density lipoprotein	51.90 (21.75)			
Total cholesterol	176.15 (35.90)			
Clinical outcomes: reduction from baseline	Control	Control	CGM	CGM
	Low baseline HbA1c (<8.5%)	High baseline HbA1c (≥8.5%)	Low baseline HbA1c (<8.5%)	High baseline HbA1c (≥8.5%)
HbA1c reduction	0.22 (0.78)	0.53 (0.60)	0.63 (0.59)	1.29 (0.77)
Average annual rate of NSHE	131.4	100.6	85.9	100.6

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Supplementary Table 6. Cost parameters for the long-term cost-effectiveness model

Definition	Base-Case Value (2015 USD)	References
Blood glucose monitoring^a related costs		
Daily blood glucose monitoring (CGM)		See Table 3
Daily blood glucose monitoring (control)		See Table 3
Kidney related costs		
Microalbuminuria	21.75	St Charles et al, 2009
Macroalbuminuria	32.01	St Charles et al, 2009
End-stage renal disease	109,315.22	Beckwith et al, 2012 ¹⁴
Neuropathy related costs		
Neuropathy	1,443.79	Beckwith et al, 2012
Amputation, year of event	55,688.88	Beckwith et al, 2012
Amputation, year 2+ after event	1,959.42	Beckwith et al, 2012
Eye related costs		
Background diabetes retinopathy	9,551.63	Li et al, 2013 ¹⁵
Proliferative diabetes retinopathy	13,802.06	Li et al, 2013
Macular edema	8,640.82	Li et al, 2013
Blindness	4,716.18	St Charles et al, 2009
Cataract	3,275.50	Palmer et al, 2004 ¹⁶
Cardiovascular complication costs		
Myocardial infarction, year of event	43,711.23	St Charles et al, 2009
Myocardial infarction, year 2+ after event	2,416.25	St Charles et al, 2009
Fatal Myocardial infarction	3,329.18	Clarke et al, 2003 (UKPDS 65) ¹⁷
Stroke, year of event	57,885.35	St Charles et al, 2009
Stroke, year 2+ after event	19,318.56	St. Charles et al, 2009
Fatal stroke	9,007.58	UKPDS 65
Heart failure, year of event	17,693.98	McQueen et al, 2011 ¹⁸
Heart failure, year 2+ after event	1,858.42	McQueen et al, 2011
Fatal heart failure	13,349.89	UKPDS 65
Angina, year of event	8,671.93	St Charles et al, 2009
Angina, year 2+ after event	3,754.94	St Charles et al, 2009
Glycemic control relate costs		
Severe hypoglycemia	1,391.14	St Charles et al, 2009
Non-severe hypoglycemia	20.32	Foos et al, 2015 ¹⁹
Hyperglycemia	15,657.10	St Charles et al, 2009

^a Blood glucose monitoring costs include costs of test strips and CGM sensor, transmitter, and receiver for the initial purchase and replacements. Because CGM did not modify insulin intake, the cost of insulin was excluded.

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Supplementary Table 7. Health-utility parameters for the long-term cost-effectiveness model

Event/state	Utility/disutility ^{a,b}	References
Diabetes no complication (CGM, control)	0.916	Trial data
Kidney related events/states		
End-stage renal disease	0.552	Joyce et al, 2011 ²⁰
Neuropathy related events/states		
Neuropathy	0.703	Begg et al, 2007 ²¹
Amputation, year of event ²	-0.109	Palmer et al, 2004
Amputation, year 2+ after event	0.766	Clarke et al, 2002 ²²
Eye related costs		
Proliferative diabetes retinopathy	0.894	Begg et al, 2007
Macular edema	0.89	Begg et al, 2007
Blindness	0.826	Clarke et al, 2002
Cardiovascular complication events/states		
Myocardial infarction, year of event	-0.129	Clarke et al, 2002
Myocardial infarction, year 2+ after event	0.82	Clarke et al, 2002
Stroke, year of event	-0.181	Clarke et al, 2002
Stroke, year 2+ after event	0.614	Clarke et al, 2002
Heart failure, year of event	-0.129	Clarke et al, 2002
Heart failure, year 2+ after event	0.829	Clarke et al, 2002
Angina	0.768	Clarke et al, 2002
Glycemic control related events		
Severe hypoglycemia event	-0.0052	N.I.C.E., 2002 ²³
Non-severe hypoglycemia event ^c	-0.00045	N.I.C.E., 2002 and Harris et al, 2014 ²⁴
Hyperglycemia event	-0.001	Walters et al, 2006 ²⁵

^a Negative values indicate *per episode disutilities* of events, and positive values indicate *annual utilities of health-states*. For events that may happen more than once per year (e.g., glycemic control related events), the disutilities were multiplied by the event count.

^b Literature based utilities were adjusted to reflect health-utilities observed in the trial.

^c Harris et al, 2014²⁴ report disutilities of -0.0056 and -0.003 for day-time and nocturnal non-severe hypoglycemia, and -0.0592 and -0.0277 for day-time and nocturnal severe hypoglycemia, respectively. We calculated the disutility of an episode of non-severe hypoglycemia by multiplying the severe hypoglycemia disutility in N.I.C.E., 2002 by the ratio of severe and non-severe hypoglycemia disutilities reported in Harris et al, 2014²⁴ (approximately 10%).

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Supplementary Table 8. Parameters for subgroup and one-way sensitivity analyses

Scenario	Parameter of interest	Parameter values	
		Lower Assumed Value	Higher Assumed Value
Sensitivity Analysis			
1	HbA1c Reduction Difference $\pm 50\%$	CGM HbA1c reduction	Baseline HbA1c ≥ 8.5 subgroup: 0.63 Baseline HbA1c < 8.5 subgroup: 0.43
2	Gold Study HbA1c Reductions ^a	HbA1c reduction	CGM: 0.68 SMBG: 0.25
3	NSHE Disutility	Non-severe hypoglycemia disutility (per episode)	0
4	Dexcom G5 CGM Cost ^b	CGM annual cost	Purchase year: \$6,789.88 Subsequent years: \$6,548.79
5	Dexcom G4 CGM Real World Use ^{b,c}	CGM annual cost	\$4,602.00
6	Dexcom G5 CGM Real World Use ^{b,c}	CGM annual cost	Purchase year: \$5,125.65 Subsequent years: \$4,884.57
7	CGM Device Annual Cost $\pm 25\%$	CGM annual cost	\$4,920.42
			\$8,200.70
Subgroup Analysis			
8	Baseline HbA1c (≤ 8.5 vs >8.5) ^d	Baseline HbA1c (modifying HbA1c reduction & NSHE annual rate)	Baseline HbA1c ≤ 8.5 subgroup Baseline HbA1c >8.5 subgroup
9	Baseline HbA1c (≤ 8.5 and >8.5) + Real World Use ^d	CGM annual cost and baseline HbA1c	Baseline HbA1c ≤ 8.5 subgroup CGM annual cost: \$4,602.00 Baseline HbA1c >8.5 subgroup CGM annual cost: \$4,602.00

^a An average 0.43% reduction in HbA1c, difference in difference, was observed in the GOLD study,²⁶ which used an earlier version of Dexcom G4 CGM without updated software 505 (considered a key-step evolution of the device²⁷).

^b See eTable 4 in the Supplement for detailed information about cost calculations.

^c See eTable 4 in the Supplement for detailed information about cost calculations.

^d Real-world CGM use as observed in the REPLACE-BG trial.¹²

Low baseline HbA1c subgroup: Average HbA1c reduction for CGM and SMBG patients was 0.53 and 0.22, respectively, and average NSHE annual rate for CGM and SMBG was 78.83 and 125.36, respectively. **High baseline HbA1c subgroup:** Average HbA1c reduction for CGM and SMBG patients was 1.29 and 0.63, respectively, and average NSHE annual rate for CGM and SMBG patients was 103.80.

^e The value -0.00225 was obtained by multiplying the base-case disutility by 5 (shown in eTable 7) to reach the overall annual disutility of -5%.²⁸

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Supplementary Table 9. Within-trial healthcare utilization results

Outcomes in utilization	SMBG (N=53)			CGM (N=105)			p-value ^a
	Mean	SD	Median (range)	Mean	SD	Median (range)	
Diabetes self-care during the 6-month trial							
N of daily strip tests	4.13	1.43	4 (2, 9)	3.37	1.18	3 (1, 7)	<0.01
Insulin dosing	61.2	33	56 (16, 190)	64.2	29	57 (24, 155)	0.33
Clinical trial staff encounters within the 6-month trial							
Physician	1.60	4.23	1 (0, 30)	0.93	1.44	0 (0, 10)	0.36
Advanced	0.19	0.68	0 (0, 4)	0.14	0.47	0 (0, 2)	0.87
Nurse	0.00	0.00	0 (0, 0)	0.09	0.42	0 (0, 3)	0.10
Educator	0.19	0.65	0 (0, 4)	0.19	0.63	0 (0, 4)	0.94
Other	0.70	2.23	0 (0, 12)	0.43	1.23	0 (0, 7)	0.80
Number of overall healthcare uses during the trial							
ER visits	0.1	0.35	0 (0, 2)	0.09	0.38	0 (0, 3)	0.87
911 call	0.00	0.00	0 (0, 0)	0.02	0.14	0 (0, 1)	0.31
Ambulance	0.00	0.00	0 (0, 0)	0.02	0.14	0 (0, 1)	0.31
Urgent care	0.02	0.14	0 (0, 1)	0.06	0.24	0 (0, 1)	0.26
Length of stay in hospital	0.40	2.88	0 (0, 21)	0.06	0.37	0 (0, 3)	0.72
Hospitalization	0.04	0.27	0 (0, 2)	0.03	0.17	0 (0, 1)	0.71
Healthcare provider	2.17	2.73	1 (0, 11)	2.02	2.22	2 (0, 11)	0.86
HbA1c test requested by health provider	0.70	0.89	0 (0, 4)	0.60	0.75	0 (0, 3)	0.62
Dietician use	0.28	0.66	0 (0, 3)	0.22	0.73	0 (0, 6)	0.38
Patients' work if they were employed during the trial							
N of missed workdays	0.21	0.82	0 (0, 4)	0.27	2.28	0 (0, 23)	0.65
N of workdays with < 50% productivity	0.15	0.60	0 (0, 3)	0.28	1.13	0 (0, 7)	0.63

^a A Wilcoxon rank-sum test was used to compare the two groups.

Supplementary Table 10. One-way sensitivity analysis results for various durations of CGM use

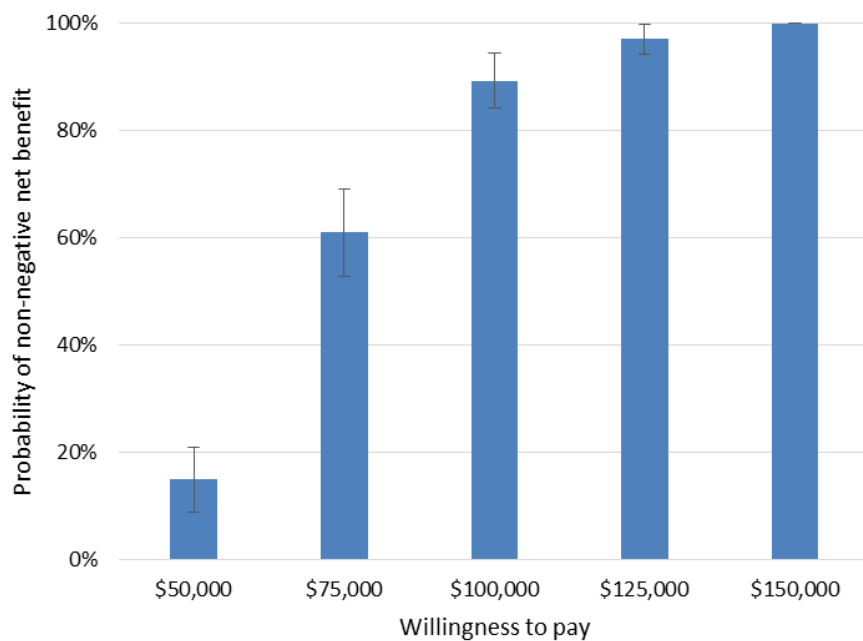
Duration of CGM use (year) ^c	DiD ^a in Costs ± MoE ^b	DiD in Life Expectancy ± MoE	DiD in QALYs ± MoE	ICER ± MoE
5	15,182 ± 1,195	0.21 ± 0.04	0.20 ± 0.02	74,136 ± 7,969
10	27,498 ± 1,179	0.34 ± 0.04	0.31 ± 0.02	89,970 ± 5,851
15	36,272 ± 1,224	0.44 ± 0.04	0.39 ± 0.02	92,023 ± 4,591
20	42,008 ± 1,199	0.51 ± 0.04	0.45 ± 0.02	93,613 ± 4,181
25	46,981 ± 1,183	0.57 ± 0.04	0.48 ± 0.02	96,919 ± 3,907

^a DiD = Difference in difference

^b MoE = Margin of error of a 95% confidence interval

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Supplementary Figure 1. PSA cost-effectiveness acceptability curve



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References

1. Thokala P, Kruger J, Brennan A, et al. Assessing the cost-effectiveness of type 1 diabetes interventions: the Sheffield type 1 diabetes policy model. *Diabet Med*. 2014;31(4):477-486.
2. Sanders GD, Neumann PJ, Basu A, et al. Recommendations for Conduct, Methodological Practices, and Reporting of Cost-effectiveness Analyses: Second Panel on Cost-Effectiveness in Health and Medicine. *JAMA*. 2016;316(10):1093-1103.
3. Husereau D, Drummond M, Petrou S, et al. Consolidated Health Economic Evaluation Reporting Standards (CHEERS) statement. *Value Health*. 2013;16(2):e1-5.
4. Bureau of Labor Statistics USDoL. Usual weekly earnings of wage and salary workers fourth quarter 2016. 2016.
5. Mehrotra A, Liu H, Adams JL, et al. Comparing costs and quality of care at retail clinics with that of other medical settings for 3 common illnesses. *Annals of internal medicine*. 2009;151(5):321-328.
6. Association NEN. 9-1-1 Surcharge--User Fees by State. 2017.
7. Taubman SL, Allen HL, Wright BJ, Baicker K, Finkelstein AN. Medicaid increases emergency-department use: evidence from Oregon's Health Insurance Experiment. *Science*. 2014;343(6168):263-268.
8. Office USGA. Ambulance Providers: Costs and Medicare Margins Varied Widely; Transports of Beneficiaries Have Increased. *UNT Libraries Government Documents Department*. 2012.
9. Pfunter A, Wier LM, Steiner C. Costs for Hospital Stays in the United States, 2010: Statistical Brief #146. *Healthcare Cost and Utilization Project (HCUP) Statistical Briefs*. Rockville (MD)2006.
10. Ward A, Alvarez P, Vo L, Martin S. Direct medical costs of complications of diabetes in the United States: estimates for event-year and annual state costs (USD 2012). *J Med Econ*. 2014;17(3):176-183.
11. St Charles M, Lynch P, Graham C, Minshall ME. A cost-effectiveness analysis of continuous subcutaneous insulin injection versus multiple daily injections in type 1 diabetes patients: A third-party US payer perspective. *Value in Health*. 2009;12(5):674-686.
12. Aleppo G, Ruedy KJ, Riddlesworth TD, et al. REPLACE-BG: A Randomized Trial Comparing Continuous Glucose Monitoring With and Without Routine Blood Glucose Monitoring in Well-Controlled Adults With Type 1 Diabetes. *Diabetes Care*. 2017;dc162482.
13. Garg SK, Voelmler MK, Gottlieb P. Feasibility of 10-day use of a continuous glucose-monitoring system in adults with type 1 diabetes. *Diabetes Care*. 2009;32(3):436-438.
14. Beckwith J, Nyman JA, Flanagan B, Schrover R, Schuurman HJ. A health economic analysis of clinical islet transplantation. *Clin Transplant*. 2012;26(1):23-33.
15. Li R, Bilik D, Brown MB, et al. Medical costs associated with type 2 diabetes complications and comorbidities. *The American journal of managed care*. 2013;19(5):421.
16. Palmer AJ, Roze S, Valentine WJ, et al. The CORE Diabetes Model: Projecting long-term clinical outcomes, costs and cost-effectiveness of interventions in diabetes mellitus (types 1 and 2) to support clinical and reimbursement decision-making. *Curr Med Res Opin*. 2004;20 Suppl 1:S5-26.
17. Clarke P, Gray A, Legood R, Briggs A, Holman R. The impact of diabetes-related complications on healthcare costs: results from the United Kingdom Prospective Diabetes Study (UKPDS Study No. 65). *Diabetic Medicine*. 2003;20(6):442-450.
18. McQueen RB, Ellis SL, Campbell JD, Nair KV, Sullivan PW. Cost-effectiveness of continuous glucose monitoring and intensive insulin therapy for type 1 diabetes. *Cost Effectiveness and Resource Allocation*. 2011;9(1):13.
19. Foos V, Varol N, Curtis BH, et al. Economic impact of severe and non-severe hypoglycemia in

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- patients with Type 1 and Type 2 diabetes in the United States. *Journal of medical economics*. 2015;18(6):420-432.
20. Lee JM, Rhee K, O'grady MJ, et al. Health utilities for children and adults with type 1 diabetes. *Medical care*. 2011;49(10):924.
 21. Begg S, Vos T, Barker B, Stevenson C, Stanley L, Lopez AD. The burden of disease and injury in Australia 2003. 2007.
 22. Clarke P, Gray A, Holman R. Estimating utility values for health states of type 2 diabetic patients using the EQ-5D (UKPDS 62). *Medical Decision Making*. 2002;22(4):340-349.
 23. National Institute for Clinical Excellence. Guidance on the use of long-acting insulin analogues for the treatment of diabetes insulin glargine. 2002(www.nice.org.uk/nicemedia/pdf/53_Insulin_analogues_full_guidance.pdf).
 24. Harris S, Mamdani M, Galbo-Jørgensen CB, Bøgelund M, Gundgaard J, Groleau D. The effect of hypoglycemia on health-related quality of life: Canadian results from a multinational time trade-off survey. *Canadian journal of diabetes*. 2014;38(1):45-52.
 25. Walters N, Gordois A, Brown A, Lindsay P, Gonzalo F, Comas S. Quantifying the impact of fear of hypoglycemia on quality of life. *Value in Health*. 2006;9(6):A238.
 26. Lind M, Polonsky W, Hirsch IB, et al. Continuous Glucose Monitoring vs Conventional Therapy for Glycemic Control in Adults With Type 1 Diabetes Treated With Multiple Daily Insulin Injections: The GOLD Randomized Clinical Trial. *JAMA*. 2017;317(4):379-387.
 27. Laffel L. Improved Accuracy of Continuous Glucose Monitoring Systems in Pediatric Patients with Diabetes Mellitus: Results from Two Studies. *Diabetes Technol Ther*. 2016;18 Suppl 2:S223-233.
 28. Marrett E, Stargardt T, Mavros P, Alexander CM. Patient-reported outcomes in a survey of patients treated with oral antihyperglycaemic medications: associations with hypoglycaemia and weight gain. *Diabetes Obes Metab*. 2009;11(12):1138-1144.