

References

E-15

1. ECRI Institute. Ultrasonic-strip (U-Strip) transdermal insulin delivery system for treating diabetes. Plymouth Meeting (PA): ECRI Institute; 2016.
2. Beck R, Riddlesworth T, Ruedy K, et al. Effect of continuous glucose monitoring on glycemic control in adults with type 1 diabetes using insulin injections. *JAMA*. 2017;317(4):371-378.
3. Department of Health and Human Services. Medicare and Medicaid services. 52976 Federal Register. Vol. 82, No. 219. 2017.
4. Hayes, Inc. Hayes Health Technology Brief. Continuous glucose monitoring systems. Lansdale, PA: Hayes, Inc.; 07/01/2017.
5. Hayes, Inc. Hayes Health Technology Brief. FreeStyle Libre Flash glucose monitoring system for maintaining glycemic control in adults with diabetes mellitus. Lansdale, Pa: Hayes, Inc.; 09/04/2018.
6. Hayes, Inc. Hayes Search and Summary. OmniPod insulin management system. Lansdale, Pa: Hayes, Inc.; 10/01/2018.
7. Hayes, Inc. Hayes Health Technology Brief.V-Go Disposable Insulin Delivery Device for the Management of Type 1 or Type 2 Diabetes Mellitus. Lansdale, Pa: Hayes, Inc.; 10/24/2018.
8. National Institute for Health and Care Excellence (NICE). Type 1 diabetes in adults: Diagnosis and management. London, UK: National Institute for Health and Care Excellence; 2015. Updated 2016. NICE Guideline No. 17.
9. Karges B, Schwandt A, Heidtmann B, et al. Association of insulin pump therapy vs insulin injection therapy with severe hypoglycemia, ketoacidosis, and glycemic control among children, adolescents, and young adults with type 1 diabetes. *JAMA*. 2017;318(14):1358-1366.
10. Cohen O, Valentine W. Do we need updated guidelines on the use of insulin pump therapy in type 2 diabetes? A review of national and international practice guidelines. *J Diabetes Sci Technol*. 2016;10(6):1388-98.
11. Sutton D, Higdon CD, Nikkel C, et al. Clinical benefits over time associated with use of V-Go wearable insulin delivery device in adult patients with diabetes: A retrospective analysis. *Adv Ther*. 2018;35(5):631-643.

12. Layne JE, Parkin CG, Zisser H. Efficacy of the Omnipod insulin management system on glycemic control in patients with type 1 diabetes previously treated with multiple daily injections or continuous subcutaneous insulin infusion. *J Diabetes Sci Technol*. 2016;10(5):1130-5.
13. Polonsky WH, Hessler D, Layne JE, et al. Impact of the Omnipod® Insulin Management System on quality of life: A survey of current users. *Diabetes Technol. Ther.* 2016;18(10):664-70.
14. Ly TT, Layne JE, Huyett LM, et al. Novel Bluetooth-enabled tubeless insulin pump: innovating pump therapy for patients in the digital age. *J Diabetes Sci Tech*. 2019;13(1):20-6.
15. Danne T, Schwandt A, Biester T, et al for the DPV Initiative. Long-term study of tubeless insulin pump therapy compared to multiple daily injections in youth with type 1 diabetes: Data from the German/Austrian DPV registry. *Pediatr Diabetes*. 2018;19(5):979-84.
16. American Diabetes Association. 7. Diabetes technology: Standards of medical care in diabetes 2020. *Diabetes Care*. 2020;43(Suppl 1):S77-S88.
17. American Diabetes Association. 6. Glycemic Targets: Standards of Medical Care in Diabetes 2019. *Diabetes Care*. 2019;42(Suppl 1):S61-S70.
18. Forlenza GP, Li Z, Buckingham BA, Pinsker JE, Cengiz E, et al. Predictive low-glucose suspend reduces hypoglycemia in adults, adolescents, and children with type 1 diabetes in an at-home randomized crossover study: Results of the PROLOG trial. *Diabetes Care*. 2018;41(10):2155-2161.
19. Food and Drug Administration (FDA). Premarket Approval (PMA): MINIMED 530G SYSTEM. 2013.
20. Food and Drug Administration (FDA). Premarket Approval (PMA): MINIMED 630G SYSTEM WITH SMARTGUARD(TM). 2016.
21. Food and Drug Administration (FDA). Premarket Approval (PMA): MiniMed 670G System. 2016.
22. Food and Drug Administration (FDA). t:slim X2 Insulin Pump with Basal-IQ Technology Premarket Approval. 2018.
23. Faulds ER, Zappe J, Dungan KM. Real-world implications of hybrid close loop (HCL) insulin delivery system. *Endocr Pract*. 2019;25(5):477-484.

24. Forlenza GP, Pinhas-Hamiel O, Liljenquist DR, et al. Safety evaluation of the MiniMed 670G system in children 7-13 years of age with type 1 diabetes. *Diabetes Technol Ther.* 2019;21(1):11-19.
25. Bergenstal RM, Garg S, Weinzimer SA, et al. Safety of a hybrid closed-loop insulin delivery system in patients with type 1 diabetes. *JAMA.* 2016;316(13):1407-1408.
26. Forlenza GP, Ekhlaspour L, Breton M, Maahs DM, et al. Successful at-home use of the tandem control-iq artificial pancreas system in young children during a randomized controlled trial. *Diabetes Technol Ther.* 2019;21(4):159-169.
27. Garg SK, Weinzimer SA, Tamborlane WV, Buckingham BA, Bode BW, et al. Glucose outcomes with the in-home use of a hybrid closed-loop insulin delivery system in adolescents and adults with type 1 diabetes. *Diabetes Technol Ther.* 2017;19(3):155-163.
28. Beato-Víbora PI, Gallego-Gamero F, Lázaro-Martín L, Romero-Pérez MDM, et al. Prospective analysis of the impact of commercialized hybrid closed-loop system on glycemic control, glycemic variability, and patient-related outcomes in children and adults: A focus on superiority over predictive low-glucose suspend technology. *Diabetes Technol Ther.* 2020;22(12):912-919.
29. Tauschmann M, Thabit H, Bally L, Allen JM, Hartnell S, et al. Closed-loop insulin delivery in suboptimally controlled type 1 diabetes: A multicentre, 12-week randomised trial. *Lancet.* 2018;392(10155):1321-1329.
30. Wood MA, Shulman DI, Forlenza GP, Bode BW, Pinhas-Hamiel et al. In-clinic evaluation of the MiniMed 670G System "suspend before low" feature in children with type 1 diabetes. *Diabetes Technol Ther.* 2018;20(11):731-737.
31. Abraham MB, Nicholas JA, Smith GJ, et al. Reduction in hypoglycemia with the predictive lowglucose management system: A long-term randomized controlled trial in adolescents with type 1 diabetes. *Diabetes Care.* 2018;41(2):303-310.
32. Messer LH, Forlenza GP, Sherr JL, Wadwa RP, et al. Optimizing hybrid closed-loop therapy in adolescents and emerging adults using the MiniMed 670G System. *Diabetes Care.* 2018;41(4):789-796.
33. Brown SA, Kovatchev BP, Raghinaru D, Lum JW, et al. Six-month randomized, multicenter trial of closed-loop control in type 1 diabetes. *N Engl J Med.* 2019;381(18):1707-1717.
34. Gómez AM, Marín Carrillo LF, Muñoz Velandia OM, et al. Long-term efficacy and safety of sensor augmented insulin pump therapy with

low-glucose suspend feature in patients with type 1 diabetes. *Diabetes Technol Ther.* 2017;19(2):109-114.

35. Hayes, Inc. Hayes Health Technology Assessment. Artificial pancreas with the t:slim X2 for the management of diabetes mellitus. Lansdale, PA: Hayes, Inc. 11/17/2020.
36. Hayes, Inc. Hayes Health Technology Assessment. Artificial pancreas with the Minimed 670g for the management of diabetes mellitus. Lansdale, PA: Hayes, Inc.; 11/06/2020.
37. Hayes, Inc. Hayes Health Technology Assessment. Continuous subcutaneous insulin infusion with Omnipod insulin management system (insulet corporation) for management of diabetes mellitus. Lansdale, PA: Hayes, Inc.; 01/23/2020.
38. Hayes, Inc. Hayes Health Technology Assessment. Eversense continuous glucose monitor for maintaining glycemic control in adults with diabetes mellitus. Lansdale, PA: Hayes, Inc.; 09/14/2018.
39. Fonseca V, Grunberger G, Anhalt H, et al. Continuous glucose monitoring: A consensus conference of the American Association of Clinical Endocrinologists (AACE) and the American College of Endocrinology (ACE). *Endocr Pract.* 2016;22(8):1009-1021.
40. Trevitt S, Simpson S, Wood, A. Artificial pancreas device systems for the closed-loop control of type 1 diabetes: What systems are in development? *J Diabetes Sci Technol.* 2016;10(3):714–723.
41. Bailey T, Grunberger G, Bode B, et al. American Association of Clinical Endocrinologists and American College of Endocrinology 2016 outpatient glucose monitoring consensus statement. *Endocr Pract.* 2016;22(2):231-261.
42. Peters A, Ahmann A, Battelino T, et al. Continuous subcutaneous insulin infusion therapy and continuous glucose monitoring in adults: An Endocrine Society clinical practice guideline. *J Clin Endocrinol Diabetes.* 2016;101(11):3922-3937.
43. American Association of Clinical Endocrinologists and American College of Endocrinology. Consensus Statement on continuous glucose monitoring. 2016.
44. Kropff J, Choudhary P, Barnard K, Bain S, Neupane S. Accuracy and longevity of an implantable continuous glucose sensor in the PRECISE study: A 180-day prospective, multicenter, pivotal trial. *Diabetes Care.* 2017;40:63–68.
45. Christiansen M, Klaff L, Brazg R, et al. A prospective multicenter evaluation of the accuracy of a novel implanted continuous glucose sensor: PRECISE II. *Diabetes Technol Ther.* 2018;20(3):197–206.

46. Sanchez P, Ghosh-Dastidar S, Tweden KS, Kaufman FR. Real-world data from the first US commercial users of an implantable continuous glucose sensor. *Diabetes Technol Ther.* 2019; 21(12):677-81.
47. Deiss D, Szadkowska A, Gordon D, et al. Clinical practice recommendations on the routine use of Eversense, the first long-term implantable continuous glucose monitoring system. *Diabetes Technol Ther.* 2019;21(5):254-64.
48. Bolinder J, Antuna R, Geelhoed-Duijvestijn P, et al. Novel glucose-sensing technology and hypoglycaemia in type 1 diabetes: A multicentre, non-masked, randomized controlled trial. *The Lancet.* 2016;388(10057):2254-63.
49. De Ridder F, den Brinker M, De Block C. The road from intermittently scanned glucose monitoring to hybrid closed-loop systems: Part A. Keys to success: Subject profiles, choice of systems, education. *Ther Adv Endocrinol Metab.* 2019;10:2042018819865399.
50. Heald AH, Yadegarfar G, Anderson SG, etc. The FreeStyle Libre flash glucose monitoring system: How it has improved glycaemic control for people with type 1 diabetes in Eastern Cheshire, UK. *J Diabetes Nurs.* 2019;23(3).
51. Fokkert MJ, Van Dijk PR, Edens MA, et al. Performance of the FreeStyle Libre Flash glucose monitoring system in patients with type 1 and 2 diabetes mellitus. *BMJ Open Diabetes Res Care.* 2017;5(1):e000320.
52. Ólafsdóttir AF, Attvall S, Sandgren U, et al. A clinical trial of the accuracy and treatment experience of the flash glucose monitor FreeStyle Libre in adults with type 1 diabetes. *Diabetes Technol Ther.* 2017;19(3):164-72.
53. American Diabetes Association (ADA). 6. Glycemic Targets. *Diabetes Care.* 2017;40(Suppl 1):S48-S56.
54. Garber, AA, Abrahamson, MM, Barzilay, et al. Consensus statement by the American association of clinical endocrinologist and American college of endocrinology on the comprehensive type 2 diabetes management algorithm- 2019 executive summary. *Endocr Pract.* 2019;25(1).
55. American Diabetes Association. 7. Diabetes Technology: Standards of medical care in diabetes 2019. *Diabetes Care.* 2018;42(Suppl 1).
56. Pennsylvania General Assembly. Act 98. Insurance Company Law of 1921 – Amend Reimbursement. Act of October 16, 1998.