

Updates to the *Standards of Medical Care in Diabetes—2018*

American Diabetes Association

The American Diabetes Association's (ADA's) *Standards of Medical Care in Diabetes* (Standards of Care) provide the latest in comprehensive, evidence-based recommendations for the diagnosis and treatment of children and adults with type 1, type 2, or gestational diabetes mellitus; strategies to improve the prevention or delay of type 2 diabetes; and therapeutic approaches that reduce complications and positively affect health outcomes. New in 2018, the ADA is updating and revising the online version of the Standards of Care throughout the year with annotations for new evidence or regulatory changes that merit immediate incorporation (1). The annotated Standards of Care issue is available online at care.diabetesjournals.org/content/41/Supplement_1. Updates to the 2018 Standards of Care appear below and can be accessed by clicking on the yellow highlighted text in the online issue. More information about the "living" Standards of Care, including the methodology used for reviewing and approving updates, is available at care.diabetesjournals.org/living-standards.

Revised Hypoglycemia Definition

(Sections 6 and 14): The December 2017 issue of *Diabetes Care* featured a consensus report (2) from the ADA and others in the diabetes community on clinically meaningful outcome measures beyond A1C for type 1 diabetes, which categorized hypoglycemia into three levels. The ADA has updated Section 6 Glycemic Targets and Section 14 Diabetes Care in the Hospital of the 2018 Standards of Care to align with the hypoglycemia definitions in the consensus report (2) and thereby minimize confusion for practitioners. The following updates were approved on 10 March 2018 and added to the living Standards of Care on 11 April 2018.

Table 6.3 (p. S61)

Table 6.3 has been updated to align with the recently published Consensus Report titled: "Standardizing Clinically Meaningful Outcome Measures Beyond HbA_{1c} for Type 1 Diabetes: A Consensus Report of the American Association of Clinical Endocrinologists, the American Association of Diabetes Educators, the American Diabetes Association, the Endocrine Society, JDRF International, The Leona M. and Harry B. Helmsley Charitable Trust, the Pediatric Endocrine Society, and the T1D Exchange" (2). The consensus report categorized hypoglycemia into 3 levels as outlined in the following table:

LEVEL	GLYCEMIC CRITERIA/DESCRIPTION
Level 1	Glucose <70 mg/dL (3.9 mmol/L) and glucose ≥54 mg/dL (3.0 mmol/L)
Level 2	Glucose ≥54 mg/dL (3.0 mmol/L)
Level 3	A severe event characterized by altered mental and/or physical status requiring assistance

Suggested citation: American Diabetes Association. 6. Glycemic targets: *Standards of Medical Care in Diabetes—2018* [web annotation]. *Diabetes Care* 2018;41(Suppl. 1):S55–S64. Retrieved from https://hyp.is/wmtWGjwnEeiOWY_FhVG-zA/care.diabetesjournals.org/content/41/Supplement_1/S55

"Glucagon should be prescribed for all individuals at increased risk of clinically significant hypoglycemia, defined as blood glucose <54 mg/dL (3.0 mmol/L), so it is available should it be needed. Caregivers, school personnel, or family members of these individuals should know where it is and when and how to administer it. Glucagon administration is not limited to health care professionals. E" (p. S61)

For alignment with the annotation to Table 6.3, the above recommendation has been updated to state the following:

"Glucagon should be prescribed for all individuals at increased risk of level 2 hypoglycemia, defined as blood glucose <54 mg/dL (3.0 mmol/L), so it is available should it be needed. Caregivers, school personnel, or family members of these individuals should know where it is and when and how to administer it. Glucagon administration is not limited to health care professionals. E"

Suggested citation: American Diabetes Association. 6. Glycemic targets: *Standards of Medical Care in Diabetes—2018* [web annotation]. *Diabetes Care* 2018;41(Suppl. 1):S55–S64. Retrieved from https://hyp.is/7fVa4jwnEeiJD0vde2XXyw/care.diabetesjournals.org/content/41/Supplement_1/S55

UPDATES

“Insulin-treated patients with hypoglycemia unawareness or an episode of clinically significant hypoglycemia should be advised to raise their glycemic targets to strictly avoid hypoglycemia for at least several weeks in order to partially reverse hypoglycemia unawareness and reduce risk of future episodes. A” (p. S61)

For alignment with the annotation to Table 6.3, the above recommendation has been updated to state the following:

“Insulin-treated patients with hypoglycemia unawareness or an episode of level 2 (<54 mg/dL [3.0 mmol/L]) hypoglycemia should be advised to raise their glycemic targets to strictly avoid hypoglycemia for at least several weeks in order to partially reverse hypoglycemia unawareness and reduce risk of future episodes. A”

Suggested citation: American Diabetes Association. 6. Glycemic targets: *Standards of Medical Care in Diabetes—2018* [web annotation]. *Diabetes Care* 2018;41(Suppl. 1):S55–S64. Retrieved from https://hyp.is/DIadcjwoEeiDyj_McVdDvg/care.diabetesjournals.org/content/41/Supplement_1/S55

“Recommendations from the International Hypoglycemia Study Group regarding the classification of hypoglycemia in clinical trials are outlined in Table 6.3 (75). Of note, this classification scheme considers a blood glucose <54 mg/dL (3.0 mmol/L) detected by SMBG, CGM (for at least 20 min), or laboratory measurement of plasma glucose as sufficiently low to indicate clinically significant hypoglycemia that should be included in reports of clinical trials of glucose-lowering drugs for the treatment of diabetes (75). However, a hypoglycemia alert value of ≤70 mg/dL (3.9 mmol/L) can be important for therapeutic dose adjustment of glucose-lowering drugs in clinical care and is often related to symptomatic hypoglycemia. Severe hypoglycemia is defined as severe cognitive impairment requiring assistance from another person for recovery.” (p. S61)

For alignment with the annotation to Table 6.3, the section of text above has been updated to state the following:

“Recommendations regarding the classification of hypoglycemia are outlined in Table 6.3. Level 1 hypoglycemia is defined as a measurable glucose concentration <70 mg/dL (3.9 mmol/L) but ≥54 mg/dL (3.0 mmol/L). A blood glucose concentration of 70 mg/dL has been recognized as a threshold for neuroendocrine responses to falling glucose in people without diabetes. Because many people with diabetes demonstrate impaired counterregulatory responses to hypoglycemia and/or experience hypoglycemia unawareness, a measured glucose level <70 mg/dL (3.9 mmol/L) is considered clinically important, independent of the severity of acute hypoglycemic symptoms. Level 2 hypoglycemia (defined as a blood glucose concentration <54 mg/dL [3.0 mmol/L]) is the threshold at which neuroglycopenic symptoms begin to occur, and requires immediate action to resolve the hypoglycemic unawareness or an episode of a clinically significant event. Lastly, level 3 hypoglycemia is defined as a severe event characterized by altered mental and/or physical functioning that requires assistance from another person for recovery.”

Suggested citation: American Diabetes Association. 6. Glycemic targets: *Standards of Medical Care in Diabetes—2018* [web annotation]. *Diabetes Care* 2018;41(Suppl. 1):S55–S64. Retrieved from https://hyp.is/wZBZiDwoEeihcafMFp0hhw/care.diabetesjournals.org/content/41/Supplement_1/S55

“The hypoglycemia alert value in hospitalized patients is defined as blood glucose ≤70 mg/dL (3.9 mmol/L) (17) and clinically significant hypoglycemia as glucose values <54 mg/dL (3.0 mmol/L). Severe hypoglycemia is defined as that associated with severe cognitive impairment regardless of blood glucose level (17).” (p. S145)

For alignment with the annotation to Table 6.3, the section of text above has been updated to state the following:

“Level 1 hypoglycemia in hospitalized patients is defined as a measurable glucose concentration <70 mg/dL (3.9 mmol/L) but ≥54 mg/dL (3.0 mmol/L). Level 2 hypoglycemia (defined as a blood glucose concentration <54 mg/dL [3.0 mmol/L]) is the threshold at which neuroglycopenic symptoms begin to occur and requires immediate action to resolve the hypoglycemic event. Lastly, level 3 hypoglycemia is defined as a severe event characterized by altered mental and/or physical functioning that requires assistance from another person for recovery.”

Suggested citation: American Diabetes Association. 14. Diabetes care in the hospital: *Standards of Medical Care in Diabetes—2018* [web annotation]. *Diabetes Care* 2018;41(Suppl. 1):S144–S151. Retrieved from https://hyp.is/ah1vYjwrEeiRdH_dRhvgIA/care.diabetesjournals.org/content/41/Supplement_1/S144

New FDA-Approved Drugs

(Section 8): In December 2017, the U.S. Food and Drug Administration (FDA) approved the GLP-1 receptor agonist semaglutide and the SGLT2 inhibitor ertugliflozin as adjuncts to diet and exercise to improve glycemic control in adults with type 2 diabetes (3,4). These medications have the potential to impact patient care and have therefore been added to Section 8 - Pharmacologic Approaches to Glycemic Treatment. The following updates were approved on 10 March 2018 and added to the living Standards of Care on 11 April 2018.

Table 8.2 (p. S79)

The following note has been added to Table 8.2.

“In December 2017, the U.S. Food and Drug Administration approved the SGLT2 inhibitor ertugliflozin as an adjunct to diet and exercise to improve glycemic control in adults with type 2 diabetes. (3)”

Suggested citation: American Diabetes Association. 8. Pharmacologic approaches to glycemic treatment: *Standards of Medical Care in Diabetes—2018* [web annotation]. *Diabetes Care* 2018;41(Suppl. 1):S73–S85. Retrieved from https://hyp.is/8Qjypj2VEei_E2-Ft0MSjQ/care.diabetesjournals.org/content/41/Supplement_1/S73

Table 8.2 (p. S79)

The following note has been added to Table 8.2.

“In December 2017, the U.S. FDA approved the GLP-1 receptor agonist semaglutide as an adjunct to diet and exercise to improve glycemic control in adults with type 2 diabetes. (4)”

Suggested citation: American Diabetes Association. 8. Pharmacologic approaches to glycemic treatment: *Standards of Medical Care in Diabetes—2018* [web annotation]. *Diabetes Care* 2018;41(Suppl. 1):S73–S85. Retrieved from https://hyp.is/D0tVED2WEeiK8ZvLIDyL-Zg/care.diabetesjournal.s.org/content/41/Supplement_1/S73

Standards of Medical Care in Diabetes—2018 Abridged for Primary Care Providers

The online version of the *Standards of Medical Care in Diabetes—2018 Abridged for Primary Care Providers*, published in *Clinical Diabetes* at <https://doi.org/10.2337/cd17-0119>, has been updated to include the annotations outlined above.

References

1. Cefalu WT, Berg EG, Petersen MP, Darsow T. American Diabetes Association's Standards of Care: A paradigm shift in the dissemination of information. *Diabetes Care* 2018;41:387–388
2. Agiostratidou G, Anhalt H, Ball D, et al. Standardizing clinically meaningful outcome measures beyond HbA_{1c} for type 1 diabetes: A consensus report of the American Association of Clinical Endocrinologists, the American Association of Diabetes Educators, the American Diabetes Association, the Endocrine Society, JDRF International, The Leona M. and Harry B. Helmsley Charitable Trust, the Pediatric Endocrine Society, and the T1D Exchange. *Diabetes Care* 2017;40:1622–1630
3. U.S. Food and Drug Administration. Drugs@FDA: FDA approved drug products [Internet]. Available from <https://www.accessdata.fda.gov/scripts/cder/daf/index.cfm?event=overview.process&applno=209803>. Accessed 1 January 2018
4. U.S. Food and Drug Administration. Drugs@FDA: FDA approved drug products [Internet]. Available from <https://www.accessdata.fda.gov/scripts/cder/daf/index.cfm?event=overview.process&applno=209637>. Accessed 1 January 2018