

## References for Fall 2023 AMED PRN Newsletter

### Current Clinical Issue: SGLT2 inhibitor initiation as part of GDMT for patients with acute decompensated heart failure.

1. Writing Committee, Maddox TM, Januzzi JL Jr, et al. 2021 Update to the 2017 ACC Expert Consensus Decision Pathway for optimization of heart failure treatment: Answers to 10 pivotal issues about heart failure with reduced ejection fraction: A report of the American College of Cardiology Solution Set Oversight Committee. *J Am Coll Cardiol.* 2021;77(6):772-810. doi:10.1016/j.jacc.2020.11.022
2. Voors AA, Angermann CE, Teerlink JR, et al. The SGLT2 inhibitor empagliflozin in patients hospitalized for acute heart failure: a multinational randomized trial. *Nat Med.* 2022;28(3):568-574. doi:10.1038/s41591-021-01659-1
3. Horiuchi Y, Matsue Y, Nogi K, et al. Early treatment with a sodium-glucose co-transporter 2 inhibitor in high-risk patients with acute heart failure: Rationale for and design of the EMPA-AHF trial. *Am Heart J.* 2023;257:85-92. doi:10.1016/j.ahj.2022.12.005
4. Farxiga (dapagliflozin) [package insert]. Wilmington, DE: AstraZeneca Pharmaceuticals LP; 2023. [https://www.accessdata.fda.gov/drugsatfda\\_docs/label/2021/202293s024lbl.pdf](https://www.accessdata.fda.gov/drugsatfda_docs/label/2021/202293s024lbl.pdf). Accessed July 27, 2023.
5. Jardiance (empagliflozin) [package insert]. Ridgefield, CT: Boehringer Ingelheim Pharmaceuticals, Inc; 2022. [https://www.accessdata.fda.gov/drugsatfda\\_docs/label/2022/204629s033lbl.pdf](https://www.accessdata.fda.gov/drugsatfda_docs/label/2022/204629s033lbl.pdf). Accessed July 20, 2023.
6. INPEFA (sotagliflozin) [package insert]. The Woodlands, TX: Lexicon Pharmaceuticals, Inc; 2023. [https://www.accessdata.fda.gov/drugsatfda\\_docs/label/2023/216203s000lbl.pdf](https://www.accessdata.fda.gov/drugsatfda_docs/label/2023/216203s000lbl.pdf). Accessed July 26, 2023.
7. Ern Yeoh S, Osmanska J, Petrie MC, et al. Dapagliflozin versus metolazone in heart failure resistant to loop diuretics [published online ahead of print, 2023 May 21]. *Eur Heart J.* 2023;ehad341. doi:10.1093/eurheartj/ehad341
8. Rong X, Zhu Y, Wen B, et al. Risk of hypovolemia associated with sodium-glucose cotransporter-2 inhibitors treatment: A meta-analysis of randomized controlled trials. *Front Cardiovasc Med.* 2022;9:973129. Published 2022 Nov 14. doi:10.3389/fcvm.2022.973129
9. A randomized, open-label study of dapagliflozin in patients with or without type 2 diabetes admitted with acute heart failure. *ClinicalTrials.gov* identifier: NCT04298229. Updated June 9, 2023. Accessed July 17, 2023. <https://clinicaltrials.gov/study/NCT04298229>.

### Current Clinical Issue: Hospital Interchange for Concentrated Insulin Products

1. ElSayed NA, Aleppo G, Aroda VR, Bannuru RR, Brown FM, Bruemmer D, Collins BS, Cusi K, Das SR, Gibbons CH, Giurini JM, Hilliard ME, Isaacs D, Johnson EL, Kahan S, Khunti K, Kosiborod M, Leon J, Lyons SK, Murdock L, Perry ML, Prahalad P, Pratley RE, Seley JJ, Stanton RC, Sun JK, Woodward CC, Young-Hyman D, Gabbay RA, on behalf of the American Diabetes Association. Introduction and Methodology: Standards of Care in Diabetes-2023. *Diabetes Care.* 2023 Jan 1;46(Suppl 1):S1-S4. doi: 10.2337/dc23-Sint. PMID: 36507647; PMCID: PMC9810461.
2. 10.2337/dc23-Sint. PMID: 36507647; PMCID: PMC9810461.

3. Samson SL, Vellanki P, Blonde L, Christofides EA, Galindo RJ, Hirsch IB, Isaacs SD, Izuora KE, Low Wang CC, Twining CL, Umpierrez GE, Valencia WM. American Association of Clinical Endocrinology Consensus Statement: Comprehensive Type 2 Diabetes Management Algorithm - 2023 Update. *Endocr Pract.* 2023 May;29(5):305-340. doi: 10.1016/j.eprac.2023.02.001. PMID: 37150579.
4. Umpierrez GE, Holt EH, Einhorn D, McGill JB. CONCENTRATED INSULINS: CLINICAL UPDATE OF THERAPEUTIC OPTIONS. *Endocr Pract.* 2020 Jun;26(Suppl 3):1-12. doi: 10.4158/EP-2019-0607. Epub 2020 May 15. PMID: 32339033.
5. Woodley WD, Morel DR, Sutter DE, Pettis RJ, Bolick NG. Clinical evaluation of large volume subcutaneous injection tissue effects, pain, and acceptability in healthy adults. *Clin Transl Sci.* 2022 Jan;15(1):92-104. doi: 10.1111/cts.13109. Epub 2021 Nov 10. PMID: 34268888; PMCID: PMC8742644.
6. Riddle MC, Bolli GB, Ziemer M, Muehlen-Bartmer I, Bizet F, Home PD; EDITION 1 Study Investigators. New insulin glargine 300 units/mL versus glargine 100 units/mL in people with type 2 diabetes using basal and mealtime insulin: glucose control and hypoglycemia in a 6-month randomized controlled trial (EDITION 1). *Diabetes Care.* 2014 Oct;37(10):2755-62. doi: 10.2337/dc14-0991. Epub 2014 Jul 30. PMID: 25078900.
7. Yki-Järvinen H, Bergenstal R, Ziemer M, Wardecki M, Muehlen-Bartmer I, Boelle E, Riddle MC; EDITION 2 Study Investigators. New insulin glargine 300 units/mL versus glargine 100 units/mL in people with type 2 diabetes using oral agents and basal insulin: glucose control and hypoglycemia in a 6-month randomized controlled trial (EDITION 2). *Diabetes Care.* 2014 Dec;37(12):3235-43. doi: 10.2337/dc14-0990. Epub 2014 Sep 5. PMID: 25193531.
8. Bolli GB, Riddle MC, Bergenstal RM, Ziemer M, Sestakauskas K, Goyeau H, Home PD; on behalf of the EDITION 3 study investigators. New insulin glargine 300 U/ml compared with glargine 100 U/ml in insulin-naïve people with type 2 diabetes on oral glucose-lowering drugs: a randomized controlled trial (EDITION 3). *Diabetes Obes Metab.* 2015 Apr;17(4):386-94. doi: 10.1111/dom.12438. Epub 2015 Feb 12. PMID: 25641260; PMCID: PMC4409854.
9. Home PD, Bergenstal RM, Bolli GB, Ziemer M, Rojeski M, Espinasse M, Riddle MC. New Insulin Glargine 300 Units/mL Versus Glargine 100 Units/mL in People With Type 1 Diabetes: A Randomized, Phase 3a, Open-Label Clinical Trial (EDITION 4). *Diabetes Care.* 2015 Dec;38(12):2217-25. doi: 10.2337/dc15-0249. Epub 2015 Jun 17. PMID: 26084341.
10. Marso SP, McGuire DK, Zinman B, Poulter NR, Emerson SS, Pieber TR, Pratley RE, Haahr PM, Lange M, Brown-Frandsen K, Moses A, Skibsted S, Kvist K, Buse JB; DEVOTE Study Group. Efficacy and Safety of Degludec versus Glargine in Type 2 Diabetes. *N Engl J Med.* 2017 Aug 24;377(8):723-732. doi: 10.1056/NEJMoa1615692. Epub 2017 Jun 12. PMID: 28605603; PMCID: PMC5731244.
11. Mathieu C, Ásbjörnsdóttir B, Bajaj HS, Lane W, Matos ALSA, Murthy S, Stachlewska K, Rosenstock J. Switching to once-weekly insulin icodec versus once-daily insulin glargine U100 in individuals with basal-bolus insulin-treated type 2 diabetes (ONWARDS 4): a phase 3a, randomised, open-label, multicentre, treat-to-target, non-inferiority trial. *Lancet.* 2023 Jun 10;401(10392):1929-1940. doi: 10.1016/S0140-6736(23)00520-2. Epub 2023 May 5. PMID: 37156252.
13. Gonzalvo JD, Patel DK, Olin JL. Concentrated Insulins: A Review and Recommendations. *Fed Pract.* 2017 Oct;34(Suppl 8):S38-S43. PMID: 30766315; PMCID: PMC6375530.

14. Lindauer K, Becker R. Insulin depot absorption modeling and pharmacokinetic simulation with insulin glargine 300 U/mL. *Int J Clin Pharmacol Ther.* 2019 Jan;57(1):1-10. doi: 10.5414/CP203269. PMID: 30369394; PMCID: PMC6298133.
15. Information for health care professionals. Switching between insulin products in disaster response situations. Approved by the American Diabetes Association, the Endocrine Society and JDRF. August 2020.
16. <https://diabetes.org/sites/default/files/2020-09/Switching%20Between%20Insulin%20Products%20in%20Disaster%20Response%20Situations%202020%20-%20English.pdf>. (Accessed July 18, 2023).
17. Wulfe SD, Janzen KM, Addison J, Kelley D. Rate of Inpatient Hypoglycemia Following a 1:1 Dose Interchange Between Concentrated Insulin Glargine to Insulin Detemir. *Ann Pharmacother.* 2023 May;57(5):513-520. doi: 10.1177/10600280221119187. Epub 2022 Aug 21. PMID: 35993253.
18. Mehta R, Goldenberg R, Katselnik D, Kuritzky L. Practical guidance on the initiation, titration, and switching of basal insulins: a narrative review for primary care. *Ann Med.* 2021 Dec;53(1):998-1009. doi: 10.1080/07853890.2021.1925148. PMID: 34165382; PMCID: PMC

### Utilization of Biosimilars in Diabetes Treatment

1. Matli MC, Wilson AB, Rappsilber LM, Sheffield FP, Farlow ML, Johnson JL. The First Interchangeable Biosimilar Insulin: Insulin Glargine-yfgn. *J Diabetes Sci Technol.* 2023;17(2):490-494. doi:10.1177/19322968211067511
2. In brief: Semglee - insulin glargine interchangeable with Lantus: The Medical Letter Inc. The Medical Letter Inc. October 4, 2021;63(1634):159-60. Accessed July 11, 2023. <https://secure.medicalletter.org/TML-article-1634c>.
3. Terrie YC. Fostering the adoption of biosimilars into clinical practice. *U.S. Pharmacist – The Leading Journal in Pharmacy.* June 16, 2023;48(6):36-41. Accessed August 10, 2023. <https://www.uspharmacist.com/article/fostering-the-adoption-of-biosimilars-into-clinical-practice>.
4. Amanda Ye. Introduction to two recently approved insulin glargine biosimilars. *U.S. Pharmacist – The Leading Journal in Pharmacy.* June 16, 2022;47(6):37-42. Accessed July 17, 2023. <https://www.uspharmacist.com/article/introduction-to-two-recently-approved-insulin-glargine-biosimilars>.
5. Clinical Resource, How to Switch Insulin Products. *Pharmacist’s Letter/Pharmacy Technician’s Letter/Prescriber’s Letter.* May 2023. <https://pharmacist.therapeuticresearch.com/Content/Segments/PRL/2016/Dec/How-to-Switch-Insulin-Products-10473>.

### Clinical Pearls of Biosimilar Insulin Therapy

1. Nuha A. E., Grazia A., Vanita R. A., et al; on behalf of the American Diabetes Association, 1. Improving Care and Promoting Health in Populations: *Standards of Care in Diabetes—2023.* *Diabetes Care* 1 January 2023; 46 (Supplement\_1): S10–S18. <https://doi.org/10.2337/dc23-S001>

2. Davies M, Dahl D, Heise T, et al. Introduction of biosimilar insulins in Europe. *Diabet Med*. 2017;34(10):1340-1353. doi:10.1111/dme.13400
3. Dolinar, R., Lavernia, F., Edelman, S. A Guide to Follow-on Biologics and Biosimilars with a Focus on Insulin. *Endocrine Practice*. 2018;24(2):195-204. <https://doi.org/10.4158/EP161728.RA>
4. Biosimilar and Interchangeable Biologics: More Treatment Choices. Food and Drug Administration. Accessed July 15, <https://www.fda.gov/consumers/consumer-updates/biosimilar-and-interchangeable-biologics-more-treatment-choices>
5. Lilly Launches Rezvoglar in the US. AJMC, The Center for Biosimilars. Accessed July 15, <https://www.centerforbiosimilars.com/view/lilly-launches-rezvoglar-in-the-us>
6. Ye A. Introduction to Two Recently Approved Insulin Glargine Biosimilars. *US Pharm*. 2022;47(6):37-42.
7. Biosimilar Drug Information. Food and Drug Administration. Accessed August 14, <https://www.fda.gov/drugs/biosimilars/biosimilar-product-information>
8. Basaglar. Package insert. Eli Lilly and Company; 2015
9. Zhang RM, Puri R, McGill JB. Update on Biosimilar Insulins: A US Perspective. *BioDrugs*. 2020;34(4):505-512. doi:10.1007/s40259-020-00431-0
10. Hagen T. Biosimilars Fail to Deliver on Insulin Pricing. *wwwmanagedhealthcareexecutive.com*. 2023;33(5).
11. Insulin Coverage Under Private Health Insurance and Medicare Part D: In Brief. Congressional Research Service. Accessed July 15, <https://crsreports.congress.gov/product/pdf/R/R47409>