



Subject: Victoza (liraglutide [rDNA origin] injection)*

Effective Date: 2/22/2011

Department(s): Utilization Management

Policy: For members whose injectable medication is covered through the medical benefit, Victoza is reimbursable under Plans administered by QualCare, Inc. when medical necessity criteria specified below are met.

Objective: To ensure proper and consistent reimbursement for a medically necessary service.

Procedure: Victoza is considered medically necessary for the treatment of type II diabetes mellitus when there is documentation of all of the following:

A. The glycohemoglobin (A1c) value is greater than 7%.

And

B. Documented failure of three months use of exenatide (Byetta) to achieve an A1c of 7% or less.

Or

C. Documented intolerance to or contraindication to exenatide (Byetta).

References:

Jellinger PS. Focus on incretin-based therapies: targeting the core defects of type 2 diabetes. *Postgrad Med.* 2011 Jan;123(1):53-65

Dibonaventura MD, et al. Multinational Internet- based survey of patient preference for newer oral or injectable Type 2 diabetes medication. *Pateint Prefer Adherence.* 2010 Nov 3;4:397-406.

Buse JB, Rosenstock J, Sesti G, Schmidt WE, Montanya E, Brett JH, Zychma M, Blonde L; LEAD-6 Study Group. Liraglutide once a day versus exenatide twice a day for type 2 diabetes: a 26-week randomized, parallel-group, multinational, open-label trial (LEAD-6). *Lancet.* 2009 Jul 4;374(9683):39-47.

Russell-Jones D, Vaag A, Schmitz O, Sethi BK, Lalic N, Antic S, Zdravkovic M, Ravn GM, Simó R; Liraglutide Effect and Action in Diabetes 5 (LEAD-5) met+SU Study Group. Liraglutide vs insulin glargine and placebo in combination with metformin and sulfonylurea therapy in type 2 diabetes mellitus (LEAD-5 met+SU): a randomized controlled trial. *Diabetologia.* 2009 Oct;52(10):2046-55.

Marre M, Shaw J, Brändle M, Bebakar WM, Kamaruddin NA, Strand J, Zdravkovic M, Le Thi TD, Colagiuri S; LEAD-1 SU study group. Liraglutide, a once-daily human GLP-1 analogue, added to a sulphonylurea over 26 weeks produces greater improvements in glycaemic and weight control compared with adding rosiglitazone or placebo in subjects with Type 2 diabetes (LEAD-1 SU). *Diabet Med.* 2009 Mar;26(3):268-78.

Zinman B, Gerich J, Buse JB, Lewin A, Schwartz S, Raskin P, Hale PM, Zdravkovic M, Blonde L; LEAD-4 Study Investigators. Efficacy and safety of the human glucagon-like peptide-1 analog liraglutide in combination with metformin and thiazolidinedione in patients with type 2 diabetes (LEAD-4 Met+TZD). *Diabetes Care.* 2009 Jul;32(7):1224-30. Epub 2009 Mar 16

Garber A, Henry R, Ratner R, Garcia-Hernandez PA, Rodriguez-Pattzi H, Olvera-Alvarez I, Hale PM, Zdravkovic M, Bode B; LEAD-3 (Mono) Study Group. Liraglutide versus glimepiride monotherapy for type 2 diabetes (LEAD-3 Mono): a randomized, 52-week, phase III, double-blind, parallel-treatment trial. *Lancet.* 2009 Feb 7;373(9662):473-81.

Vilsbøll T, Zdravkovic M, Le-Thi T, Krarup T, Schmitz O, Courrèges JP, Verhoeven R, Bugánová I, Madsbad S. Liraglutide, a long-acting human glucagon-like peptide-1 analog, given as monotherapy significantly improves glycemic control and lowers body weight without risk of hypoglycemia in patients with type 2 diabetes. *Diabetes Care.* 2007 Jun;30(6):1608-10.

Drafted By/Date; MMcNeilMD 02/11/11

Approved By/Date: QMC, 02/22/11

**Consistent with Summary Plan Description (SPD). When there is discordance between this policy and the SPD, the provisions of the SPD prevail