

Berkshire West Area Prescribing Committee Policy Statement

Drug Name	Dulaglutide (Trulicity®)
Indication under review	Type 2 Diabetes Mellitus (T2DM) in adults
Policy No:	APC 129
Date of Issue:	May 2016
Review Date:	May 2019
Policy Statement: Dulaglutide (Trulicity®) is recommended as a treatment for a cohort of adult patients with T2DM. These cohorts could include patients failing to improve on treatment with lixisenatide or may include patients currently on liraglutide or weekly exenatide.	
Traffic Light Status	Amber (2nd line GPL1 agonists)
Key Points considered:	
<ul style="list-style-type: none"> • The APC supported the evidence of efficacy and safety for this treatment. • Initiation will be under the direction of Dr Gallen and other consultant endocrinologists based at Melrose House. • Dulaglutide is the 2nd line GLP1 agonist when lixisenatide is not effective or tolerated (may cause side-effects such as nausea etc). These cohorts of patients may benefit from a longer acting injection such as dulaglutide. • Dulaglutide may also be an option when daily injections are not practical. 	
<p>Reference</p> <p>The National Institute for Health and Care Excellence (NICE). Clinical guideline 87. Type 2 diabetes. The management of type 2 diabetes. 2009. Available at: https://www.nice.org.uk/guidance/cg87.</p> <p>The National Institute for Health and Care Excellence (NICE). Technology appraisal guidance 203. Liraglutide for the treatment of type 2 diabetes mellitus. 2010. Available at: http://www.nice.org.uk/guidance/ta203.</p> <p>The National Institute for Health and Care Excellence (NICE) Technology appraisal guidance 248. Exenatide prolonged-release suspension for injection in combination with oral antidiabetic therapy for the treatment of type 2 diabetes. 2012. Available at: http://www.nice.org.uk/guidance/ta248.</p> <p>The National Institute for Health and Care Excellence (NICE) Evidence Summary: new medicine. ESNM26: Type 2 diabetes: lixisenatide. 2013. Available at http://www.nice.org.uk/advice/esnm26.</p> <p>GlaxoSmithKline. Eperzan 30 mg powder and solvent for solution for injection. Summary of product characteristics</p> <p>The Health and Social Care Information Centre (HSCIC). National diabetes audit 2012–2013. Report 1: care processes and treatment targets. 2014. Available at: http://www.hscic.gov.uk/catalogue/PUB14970. Accessed December 2014.</p> <p>Korytkowski M. When oral agents fail: practical barriers to starting insulin. <i>Int J Obes</i> 2002; 26(s3): s18–s24.</p> <p>Garcia-Perez LE, Alvarez M, Dilla T, Gil-Guillen V, Orozco-Beltran D. Adherence to therapies in patients with type 2 diabetes. <i>Diabetes Ther</i> 2013; 4(2): 175–194.</p> <p>Freeman JS. Optimizing outcomes for GLP-1 agonists. <i>J Am Osteopath Assoc</i> 2011; 111(s1): s15–s20.</p> <p>Scott RM. Managing diabetes self-care when manual dexterity is limited. <i>J Diabetes Nurs</i>. 1999; 3(4): 114–118.</p> <p>De Young MB, MacConnell L, Sarin V, Trautmann M, Herbert P. 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Available at: http://www.diabetes.org.uk/Documents/Reports/Supported_self-management.pdf.</p> <p>Diabetes UK. State of the nation 2012 England. 2012. Available at: http://www.diabetes.org.uk/documents/reports/state-of-the-nation-2012.pdf.</p> <p>Hex N, Bartlett C, Wright D, Taylor M, Varley D. Estimating the current and future costs of type 1 and type 2 diabetes in the UK, including direct health costs and indirect societal and productivity costs. <i>Diabet Med</i>. 2012; 29(7): 855–862.</p> <p>Genuth S, Eastman R, Kahn R, et al. Implications of the United Kingdom prospective diabetes study. <i>Diabetes Care</i> 2002; 25(s1): s28–s32</p> <p>Davies M, Speight J. Patient-reported outcomes in trials of incretin-based therapies in patients with type 2 diabetes mellitus. <i>Diabetes Obes. Metab</i>. 2012; 14(10): 882–892.</p> <p>Matfin G, Zimmerman AG, Van Brunt K, Threlkeld R, Ignaut DA. Safe and effective use of the single-use pen for injection of once weekly dulaglutide in injection-naïve patients with type 2 diabetes. Poster presentation at: The American Diabetes Association (ADA) 74th Scientific Sessions; San Francisco, CA; June 13–17, 2014</p> <p>Nauck MA, Weinstock RS, Umpeierrez GE, et al. Efficacy and safety of dulaglutide vs. sitagliptin after 52 weeks in type 2 diabetes (AWARD-5). <i>Diabetes Care</i> 2014; 37: 2149–2158.</p> <p>Wysham C, Blevins T, Arakaki R, et al. Efficacy and safety of dulaglutide added onto pioglitazone and metformin versus exenatide in type 2 diabetes in a randomized controlled trial (AWARD-1). <i>Diabetes Care</i> 2014; 37: 2159–2167.</p> <p>Giorgino F, Benroubi M, Sun JH, Zimmerman AG, Pechtner V. Efficacy and safety of once-weekly dulaglutide vs. insulin glargine in combination with metformin and glimepiride in type 2 diabetes patients (AWARD-2). Oral presentation at: The 50th European Association for the Study of Diabetes (EASD) Annual Meeting; Vienna, Austria; September 15–19, 2014.</p> <p>Jendle J, Rosenstock J, Blonde L, et al. Better glycaemic control and less weight gain with once-weekly dulaglutide vs. once-daily insulin glargine, both combined with premeal insulin lispro, in type 2 diabetes patients (AWARD-4). Oral presentation at: The 50th European Association for the Study of Diabetes (EASD) Annual Meeting; Vienna, Austria; September 15–19, 2014.</p> <p>Umpeierrez GE, Manghi FP, Povedano ST, Shurzinske L, Pechtner V. Efficacy and safety of dulaglutide vs. metformin in type 2 diabetes (AWARD-3). <i>Diabetes Care</i> 2014; 37: 2168–2176</p> <p>Dungan KM, Povedano ST, Forest T, et al. Once-weekly dulaglutide versus once-daily liraglutide in metformin-treated patients with type 2 diabetes (AWARD-6): a randomised, open-label, phase 3, non-inferiority trial. <i>Lancet</i> 2014; 384(9951): 1349–1357.</p> <p>AstraZeneca. Byetta 5 mcg solution for injection, pre-filled pen summary of product characteristics</p> <p>Novo Nordisk. Victoza 6 mg/ml solution for injection in pre-filled pen summary of product characteristics.</p> <p>Sanofi. Lyxumia 10 micrograms solution for injection summary of product characteristics</p> <p>Bailey CJ, Day C. Diabetes therapies in renal impairment. <i>Br J Diabetes Vasc Dis</i> 2012; 12(4): 167–171.</p> <p>Royal College of Nursing. Guidance to support the implementation of The Health and Safety (Sharp Instruments in Healthcare Regulations) 2013. 2013. Available at: http://www.rcn.org.uk_data/assets/pdf_file/0008/418490/004135.pdf.</p> <p>Divino V, DeKoven M, Hallinan S, et al. Glucagon-like peptide-1 receptor agonist treatment patterns among type 2 diabetes patients in six european countries. <i>Diabetes Therapy</i> 2014; [Epub ahead of print].</p> <p>The National Institute for Health and Care Excellence (NICE). Medicines practice guidelines. Developing and updating local formularies. 2012. Available at: http://www.nice.org.uk/guidance/mpg1.</p> <p>¹ The Scottish Intercollegiate Guidelines Network (SIGN). National clinical guideline 116. Management of diabetes. 2010. Available at: http://www.sign.ac.uk/guidelines/fulltext/116/</p>	
Date taken to APC:	4 th May 2016
Date Ratified by MMC on Behalf of the Board:	18 th May 2016

Berkshire West Area Prescribing Policies serve as a guide to clinicians. This does not overrule the clinical or budgetary responsibility of clinicians when considering treatment for individual patients.

Brown	Green	Amber	Red
These drugs have been reviewed and are not considered a cost effective use of scarce NHS resources	Medicines suitable for routine use. Primary care prescribers take full responsibility for prescribing	Medicines that should be initiated or recommended by a specialist and can be continued in primary care under a shared care agreement.	Medicines which should be prescribed by specialists only