

Diabetes (type 1 and type 2) in children and young people: diagnosis and management - medicines for type 2 diabetes (update)

**Consultation on draft scope
Stakeholder comments table**

18/03/2022 – 14/04/2022

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All Wales Diabetes Patient Reference Group	General	General	Please could you look at INCLUDING Pre Diabetes of T2 in Children and Young People	<p>Thank you for your comment.</p> <p>This scope for guideline update focusses on the effectiveness of medicines in children and young people diagnosed with type 2 diabetes.</p> <p>Treatment of pre-diabetes is beyond the remit of this guideline update.</p> <p>There is not currently sufficient evidence within this area to include within the scope of this update. The area will be highlighted to the Surveillance Team at NICE for consideration in future updates of this area.</p>
All Wales Diabetes Patient Reference Group	General	General	Please could you also include Remission of T2 Diabetes in Children and Young People.	<p>Thank you for your comment.</p> <p>NG18 includes recommendations relating to education and information provision, and advice about dietary management.</p> <p>There is not currently sufficient evidence within this area to include within the scope of this update. The area will be highlighted to the Surveillance Team at NICE for consideration in future updates of this area.</p>
All Wales Diabetes Patient Reference Group	General	General	Look at the Research and scope out what knowledge is required	<p>Thank you for your comment.</p>
All Wales Diabetes Patient	General	General	There are also increased risk to those coming from an Ethnic Community for developing T2 Diabetes and this should be emphasised.	<p>Thank you for your comment.</p> <p>This has been included in the Equality Impact Assessment (EIA) completed during the scoping process, which will be</p>

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Reference Group				referred to throughout guideline development and during the drafting of recommendations. This may include specific recommendations for those included in the EIA.
All Wales Diabetes Patient Reference Group	General	General	All Regional Nations have developed a Diabetes Prevention Programme of T2 Diabetes and also have a Remission Programme for T2 Diabetes Young People could be included in this.	<p>Thank you for your comment.</p> <p>NG18 includes recommendations relating to education and information provision, and advice about dietary management.</p> <p>NICE are currently developing Weight Management: preventing, assessing and managing overweight and obesity [GID-NG10182].</p> <p>This will be highlighted to the Surveillance Team at NICE for future consideration.</p>
Association of Paediatric Emergency Medicine	General	General	Many thanks for sending this to APEM. We don't have any comments for you.	Thank you for your comment.
Diabetes UK	003	012	We think that Liraglutide (Saxenda) should also be included here as it is licensed for managing weight-loss in children who are over 12	<p>Thank you for your comment.</p> <p>Medicines in addition to metformin or where metformin is not tolerated will be reviewed – liraglutide is currently licensed for use in children >10 and will be included in this review.</p>

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				Recommendations for pharmacological interventions for obesity are covered by CG189 Obesity: identification, assessment and management
Diabetes UK	003	012	We think that the below NICE guidance on weight loss services for children and young people should also be included here: Weight management: lifestyle services for overweight or obese children and young people [PH47]	Thank you for your comment. We agree and have now included this in the section on Related NICE guidance. NICE are currently developing Weight Management: preventing, assessing and managing overweight and obesity [GID-NG10182].
Diabetes UK	004	028	Although the main focus of this review is on medicines to improve glycaemic control in children with type 2 diabetes we feel that weight loss must be closely considered alongside it as a key part of managing the condition - this is due to the link between type 2 diabetes and living with overweight or obesity in children and young people. The Type 2 spotlight in the 2019/20 NPDA reported that nearly 85% of the children and young people with type 2 diabetes were obese with only 8% of those diagnosed before the 2019/20 audit year reducing their weight to a lower BMI range, highlighting the close link between the two. The audit also found that almost half of children and young people with type 2 diabetes had high blood pressure and nearly 30% had total blood cholesterol at or above the target of 5mmol or less.	Thank you for your comment and additional information. NICE are currently developing Weight Management: preventing, assessing and managing overweight and obesity [GID-NG10182]. The scope includes BMI related outcomes, these will be included, where reported in the included studies.

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			<p>The Association of Children's Diabetes Clinician's 2022 guidelines on the management of type 2 diabetes in children notes that good glycaemic control reduces microvascular risk but does not reduce macrovascular risks in adults. The benefits of newer drug classes like GLP-1 and SGLT2i in improving weight and reducing the risk of a major cardiovascular event as well as glycaemic control in adults with type 2 diabetes is a promising development. Whilst research on these new drug classes in children and young people is limited, as the evidence base develops it is important that this review considers their wider benefits in treating this severe and complex condition.</p> <p>References:</p> <p>https://www.rcpch.ac.uk/sites/default/files/2021-11/NPDA%20Spotlight%20Report%20on%20Type%20%20Diabetes%202021.pdf</p> <p>http://www.a-c-d-c.org/wp-content/uploads/2012/08/TYpe-2-guideline-ACDC-format-publish.pdf</p>	
Diabetes UK	005	016	<p>When considering intermediate outcomes like lipid profile and blood pressure management, IPSAD's consensus guidelines support the consideration of ARB and ACE inhibitors as anti-hypertensives and recommends statin therapy for dyslipidaemia in children and well as adults.</p>	<p>Thank you for your comment and additional information.</p> <p>The evidence for use of antihypertensives and statins in children and young people with type 2 diabetes will be monitored by the surveillance team. Currently our surveillance</p>

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			Reference: IPSAD 2018 consensus guidelines	has not indicated evidence to support an update including this area.
Diabetes UK	005	022	We think that the following quality standard should also be referenced in this guideline here: Obesity in children and young people: prevention and lifestyle weight management programmes. Quality standard [QS94]	Thank you for your comment. The quality standard relates to lifestyle interventions and therefore will not be impacted by this update which focusses on pharmacological treatments.
Diabetes UK	Guideline	General	Diabetes UK welcomes this consultation and the assessment of new evidence relating to medicines to treat type 2 diabetes in children and young people. Type 2 diabetes in children and young people is a growing problem in the UK, with rates of the condition rising. The NPDA 2019/20 identified 1,560 children with type 2 diabetes and the proportion of children in the audit with the condition doubled between 2012/13 and 2019/20. It is also associated with greater insulin resistance and more rapid deterioration of beta cell function decline than type 2 diabetes in adults, with children and young people frequently presenting with complications, progressing to micro and macrovascular complications rapidly and responding poorly to treatment. We support the development of guidance that better supports good clinical practice and includes the medications other than metformin that are currently licensed to treat the condition in	Thank you for your feedback and additional information.

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			<p>children, such as insulin and Liraglutide (Victoza). This will also help identify and recommend new treatments that can improve management, reduce complications and give children and young people living with type 2 diabetes more options to choose medicines that best suit their needs.</p> <p>References: https://www.rcpch.ac.uk/resources/npda-annual-reports</p> <p>https://pubmed.ncbi.nlm.nih.gov/28589895/</p>	
NHS England and Improvement	002	002	Has the HEAT (Health Equity Assessment Toolkit) been used?	<p>Thank you for your comments.</p> <p>The Health Equity Assessment Tool was not used. An Equality Impact Assessment was prepared alongside the scope for this update following the procedure set out in Developing NICE guidelines: the manual (PMG20).</p>
NHS England and Improvement	002	020	How are children and young people being defined e.g. age, weight (this may impact on volume of distribution in the case of medication uptake)	<p>Thank you for your comment.</p> <p>Children and young people are defined as aged under 18 with a diagnosis of type 2 diabetes.</p>
NHS England and Improvement	005	015 / 020	Are children and young people involved in / their views sought during the consultation?	<p>Thank you for your comment.</p> <p>The draft scope has been available for review by groups representing children and young people.</p>

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				<p>The Guideline Development Group for this update includes lay representatives.</p> <p>Information on NICE's Public Involvement Programme is available here.</p>
NHS England and Improvement	General	General	Overall robust document and consultation	Thank you for your comment.
North Central London Joint Formulary Committee	003	009	Please can the guideline make recommendations on the use of flash glucose monitoring. Current guideline (Section 1.2.59 to 1.2.65) includes SMBG and CGM only.	<p>Thank you for your comment.</p> <p>In the latest update to NG18 published in March 2022, it noted a current a lack of evidence on the effectiveness of CGM in children and young people with type 2 diabetes. This guideline includes a research recommendation research on continuous glucose monitoring in children and young people with type 2 diabetes.</p> <p>This guideline includes a recommendation regarding flash monitoring for children and young people with type 1 diabetes (rec 1.2.61)</p>
Novo Nordisk	003	026 - 029	We would like to point out an error in the document – Technology appraisals for Dulaglutide and Semaglutide are not in development.	<p>Thank you for your comment.</p> <p>These topics were not referred to NICE for a Technology Appraisal. It was agreed the topics would be incorporated in clinical guideline update (NICE guideline 28).</p>

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				Reference to these technology appraisals have been removed from the scope document.
Novo Nordisk	General	General	<p><u>Novo Nordisk agrees with the need for this update and with the scope in general.</u></p> <p>We suggest that the review question is broadened to acknowledge the importance of factors other than glycaemic control, such as weight reduction and the avoidance of hypoglycaemia. This will ensure the more detailed review questions are able to account for these other important factors when assessing the evidence base.</p>	<p>Thank you for your comment.</p> <p>These outcomes will be included, the draft scope includes outcomes relating to BMI and adverse effects of treatment.</p>
Novo Nordisk	General	General	<p>The recently published report 'The Young People with Type 2 Diabetes Report'¹ revealed that 60% of children with type 2 diabetes are not receiving the care they need to manage their condition. We suggest that the recommendations on medicines are accompanied by a clear recommendation that the individual and their parent/carer should be receiving specialist care and support to ensure the full range of medicines and options are discussed and made available to them.</p> <p>Reference 1.NHS Digital (2021) Young People with Type 2 Diabetes 2019-20; available from https://digital.nhs.uk/data-and-information/publications/statistical/national-diabetes-audit/young-people-with-type-2-diabetes-2019--20# [Accessed April 2022].</p>	<p>Thank you for your comment and additional information.</p> <p>NG18 includes recommendations about service provision for children and young people. with diabetes.</p> <p>NICE also provides guidance for shared decision making in NG197. This can be linked to from this guideline update if needed during the development of this update.</p>

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Novo Nordisk	General	General	<p><u>We recommend decisions are made based on named medicines and licensed preparations.</u></p> <p>As there are limited licensed options in children and young people for medicines to be used in combination with Metformin or as monotherapy when Metformin cannot be used, it is important for NICE to be prepared to make recommendations for named medicines rather than classes of medicines. The NICE Guidelines Manual states that recommendations for off label use of a licensed medicines should only happen "if there is good evidence for this use, and there is no other medicine licensed for the indication"¹</p> <p>Currently liraglutide is the only medicine other than insulin and Metformin, licensed for use in children over 10 years.²</p> <p>References 1. NICE (2014, updated 2022) Developing NICE guidelines: the manual. Available from https://www.nice.org.uk/process/pmg20/resources/developing-nice-guidelines-the-manual-pdf-72286708700869; [Accessed April 2022.] 2. Novo Nordisk Limited; Victoza® Summary of Product Characteristics: Available from https://www.medicines.org.uk/emc/medicine/21986#grf; [Accessed April 2022.]</p>	<p>Thank you for your comment.</p> <p>The committee will follow the NICE Guidelines Manual with regard to any recommendations for medicines.</p> <p>The scope includes the following statement: 'guideline recommendations for medicines will normally fall within licensed indications; exceptionally, and only if clearly supported by evidence, use outside a licensed indication may be recommended. The guideline will assume that prescribers will use a medicine's summary of product characteristics to inform decisions made with individual patients.'</p>

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Novo Nordisk	General	General	<p>We would like to bring to your attention an ongoing clinical trial looking at semaglutide use in the paediatric population (PIONEER TEENS), which is planned to update the label for both Ozempic® and Rybelsus®. The trial is currently ongoing.¹</p> <p>Reference 1. Novo Nordisk (in development) A Research Study to Compare a New Medicine Oral Semaglutide to a Dummy Medicine in Children and Teenagers With Type 2 Diabetes (PIONEER TEENS).</p>	<p>Thank you for your comments and additional information.</p> <p>This will be sent to the Surveillance Team at NICE for future consideration.</p>
Novo Nordisk	General	General	<p>We recommend the evidence review and the economic modelling include specific evidence of medicines which reduce hypoglycaemia. Studies included below were in the adult population and demonstrate the hypoglycaemia advantage of insulin degludec.</p> <p>The SWITCH 2 study¹ is high ranking evidence in terms of both being a randomised controlled trial but also in the fact that hypoglycaemia was the primary endpoint. The study is strong evidence for insulin degludec reducing overall, nocturnal and severe hypoglycaemia in type 2 diabetes versus glargine U100.</p> <p>The real world REFLECT study² demonstrated in a routine clinical care setting that switching to degludec from other basal insulins was associated with significantly lower rates of</p>	<p>Thank you for your comments and additional information. As these trials were in adults, please note that this update is in relation to children and young people. It is therefore unlikely that this study would meet the inclusion criteria for the review protocol.</p> <p>These outcomes will be included, the draft scope includes outcomes relating to adverse effects of treatment. medications in addition to metformin, or where metformin is not tolerated.</p>

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			<p>hypoglycemia, improved glycaemic control, and treatment satisfaction in adults with type 1 or type 2 diabetes.</p> <p>We suggest that NICE provides clear guidance that differentiates between available basal insulins, specifically taking into consideration the risk of hypoglycaemia.</p> <p>References 1.Wysham C, Bhargava A, Chaykin L et al (2017); Effect of Insulin Degludec vs Insulin Glargine U100 on Hypoglycemia in Patients With Type 2 Diabetes: The SWITCH 2 Randomized Clinical Trial. JAMA 318(1): 45-56 2.Fadini G, Feher M, Hansen T et al (2019) Switching to Degludec from Other Basal Insulins is Associated with Reduced Hypoglycemia Rates: a Prospective Study. J Clin Endocrinol Metab. 2019 Dec; 104(12): 5977–5990. Published online 2019 Aug 9. doi: 10.1210/jc.2019-01021.</p>	
Novo Nordisk	General	General	<p>In response to the question: 'Are there any cost saving interventions or examples of innovative approaches that should be considered for inclusion in this guideline?':</p> <p>As insulin devices have continued to evolve and improve, developments have expanded beyond physical upgrades and subsequently there is a growing body of evidence on the benefits of additional, software-based functionality such as memory function and connectivity with other relevant patient</p>	<p>Thank you for your comments and additional information.</p> <p>This will be sent to the Surveillance Team at NICE for future consideration. Currently our surveillance has not indicated evidence to support an update including this area.</p>

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			<p>data (for example connected smart insulin pens that can be used to record insulin doses or in combination with a patient's glucose data to help manage their diabetes)¹. This could be particularly beneficial in children who need support from their parents/carers to manage their blood sugar. The new NICE strategy recognises the emergence of new hybrid technologies and products where the impact of innovation extends beyond the use of a medicine alone. This highlights the need for future consideration of the cost-effectiveness of an insulin to assess the overall value offered to the patient and the NHS, when a particular delivery device is used in combination with the medicine and we recommend this is taken into account when developing the recommendations.</p> <p>Reference 1. Heinemann L et al 2021, Digital Diabetes Management: A Literature Review of Smart Insulin Pens. Journal of Diabetes Science and Technology. Available from https://journals.sagepub.com/doi/pdf/10.1177/1932296820983863; [Accessed April 2022]</p>	
Royal College of Nursing	General	General	We do not have any comments to add on this consultation. Thank you for the opportunity to contribute.	Thank you for your comment.
Royal College of Paediatrics	General	General	It is suggested that the updated guideline should assess the prevalence and risk of NDMA contamination of Metformin that has recently been publicised and discussed.	Thank you for your comment. This is within the remit of the MHRA:

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and Child Health				https://www.gov.uk/government/news/metformin-diabetes-medicines-mhra-update https://www.gov.uk/government/news/batch-of-metformin-oral-solution-recalled-by-mhra-due-to-nitrosamine-impurity

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