

## Putting NICE guidance into practice

### **Resource impact report: Dapagliflozin with insulin for treating type 1 diabetes (TA597)**

Published: August 2019

Following some minor changes made to the NICE technology appraisal guidance 597 in February 2020, section 1.1 of the resource impact report has been updated to reflect the changes made.

## Summary

NICE has recommended [dapagliflozin](#) with insulin as an option for treating type 1 diabetes in adults with a body mass index (BMI) of at least 27 kg/m<sup>2</sup>, when insulin alone does not provide adequate glycaemic control despite optimal insulin therapy (see [section 1](#)).

We estimate that:

- around 90,100 people with type 1 diabetes and with a BMI of at least 27 kg/m<sup>2</sup> are eligible for treatment with dapagliflozin
- not all people initiated on dapagliflozin will continue treatment. Around 40% may discontinue at 6 months in line with the guidance recommendations
- after discontinuation, around 5,400 people will have dapagliflozin by year 2023/24 once uptake has reached 10%.

The estimated annual cost of implementing this guidance based on the uptake in the resource impact assumptions is shown in table 1.

**Table 1 Estimated annual cost of implementing the guidance**

	2019/20	2020/21	2021/22	2022/223	2023/24
People having full year treatment with dapagliflozin each year <sup>1</sup>	500	1,100	2,200	4,300	5,400
Resource impact each year (£000)	332	676	1,353	2,706	3,382

<sup>1</sup> Number rounded to nearest 100

This report is supported by a [resource impact template](#) which may be used to calculate the resource impact of implementing the guidance by amending the variables.

This technology is commissioned by clinical commissioning groups. Providers are NHS Hospital trusts, community, and primary care.

# 1 Dapagliflozin

1.1 NICE has recommended [dapagliflozin](#) with insulin as an option for treating type 1 diabetes in adults with a body mass index (BMI) of at least 27 kg/m<sup>2</sup>, when insulin alone does not provide adequate glycaemic control despite optimal insulin therapy, only if:

- they are on insulin doses of 0.5 units/kg of body weight/day or more and
- they have completed a structured education programme that is evidence based, quality assured, delivered by trained educators and includes information about diabetic ketoacidosis, such as:
  - how to recognise its risk factors, signs and symptoms
  - how and when to monitor blood ketone levels
  - what actions to take for elevated blood ketones, and
- treatment is started and supervised by a consultant physician specialising in endocrinology and diabetes treatment, and haemoglobin A1c (HbA1c) levels are assessed after 6 months and regularly after this.

Stop dapagliflozin if there has not been a sustained improvement in glycaemic control (that is, a fall in HbA1c level of at least 0.3% or 3 mmol/mol).

1.2 Type 1 diabetes is an autoimmune metabolic disease that destroys insulin-producing cells of the pancreas. This raises the levels of blood glucose, which increases the risk of long-term diabetes-related complications such as retinopathy, neuropathy, cardiovascular disease and death.

1.3 The NICE guideline (NG17) on [type 1 diabetes in adults](#) recommends that people have individualised care including structured education (for example, the Dose Adjustment for Normal Eating programme), and advice on diet and physical activity (that is, lifestyle), and on managing blood glucose. The

guideline advises on targets for haemoglobin A1c (HbA1c) levels, self-monitoring of blood glucose, and preventing and managing hypoglycaemia and diabetic ketoacidosis.

- 1.4 Clinical experts suggest that people eligible for dapagliflozin would normally have completed a structured education course and may be using an insulin pump or continuous blood glucose monitoring. For people who, despite best efforts, cannot reach optimal glycaemic control, or who cannot improve control without it causing disabling hypoglycaemia, there are currently no other treatment options available.

## **2 Resource impact of the guidance**

- 2.1 We estimate that:

- around 90,100 people with type 1 diabetes and with a BMI of at least 27 kg/m<sup>2</sup> are eligible for treatment with dapagliflozin
- not all people initiated on dapagliflozin will continue treatment. Around 40% may discontinue at 6 months in line with the guidance recommendations
- after discontinuation, around 5,400 people will have dapagliflozin by year 2023/24 once uptake has reached 10%.

- 2.2 The current treatment and future uptake assumptions are based on company and published evidence and are shown in the resource impact template.

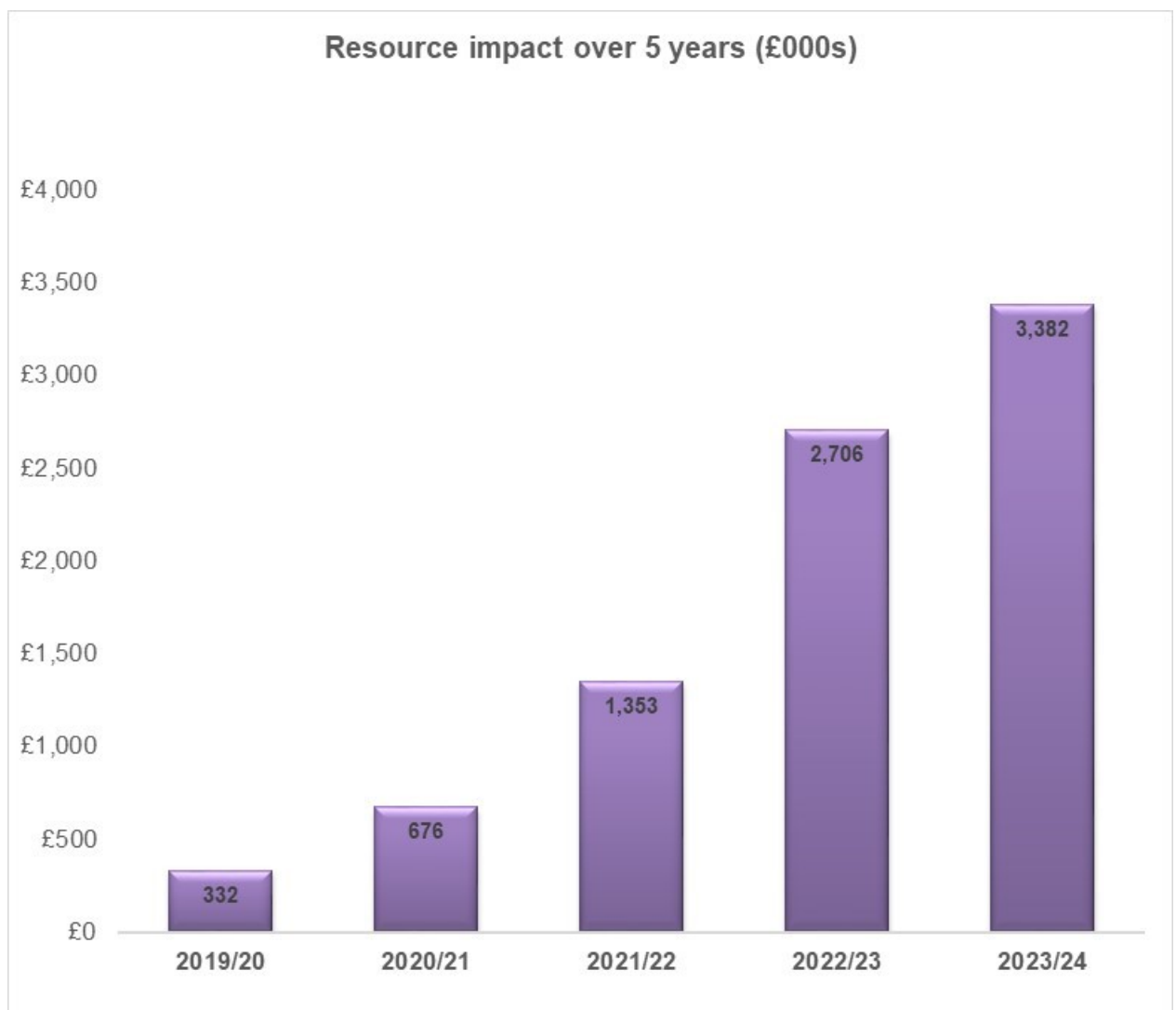
- 2.3 The estimated annual costs of implementing this guidance for the population of England based on the uptake in the resource impact assumptions are shown in table 2. The costs from year 2023/24 once steady state is reached is equivalent to around £6,100 per 100,000 population.

**Table 2 Resource impact of implementing the guidance using NICE assumptions**

	2019/20	2020/21	2021/22	2022/23	2023/24
People having full year treatment with dapagliflozin each year <sup>1</sup>	500	1,100	2,200	4,300	5,400
Resource impact each year (£000)	332	676	1,353	2,706	3,382

<sup>1</sup> Number rounded to nearest 100

2.4 The graph below shows the resource impact of dapagliflozin over 5 years.



This report is supported by a [resource impact template](#) which may be used to calculate the resource impact of implementing the guidance by amending the variables.

### **3 Implications for commissioners**

3.1 This technology is commissioned by clinical commissioning groups. Providers of care for treating type 1 diabetes are NHS hospital trusts, community, and primary care.

3.2 Dapagliflozin falls within the programme budgeting category PBC 04A: Diabetes.

### **4 How we estimated the resource impact**

#### ***The population***

4.1 Based on the [Quality and Outcomes Framework 2017-18](#), the prevalence of diabetes mellitus is 6.8% (3 million people aged 18 years and over) in England.

4.2 Table 3 shows the number of people eligible for treatment with dapagliflozin.

**Table 3 Number of people eligible for treatment in England**

Population	Proportion of previous row (%)	Number of people
Adult population in England		43,752,473
Prevalence of diabetes mellitus <sup>1</sup>	6.8	2,975,200
People with type 1 diabetes mellitus <sup>2</sup>	8.0	238,000
People with type 1 diabetes mellitus and a recorded body mass index (BMI) at least 27 kg/m <sup>2</sup> <sup>3</sup>	60.0	142,800
People with type 1 diabetes mellitus and a recorded BMI of at least 27 kg/m <sup>2</sup> whose insulin alone does not provide adequate glycaemic control despite optimal insulin therapy <sup>3</sup>	70.1	100,100
People with inadequate glycaemic control despite optimal insulin therapy who are on insulin doses of more than 0.5 units/kg of body weight/day <sup>4</sup>	90.0	90,100
Total number of people estimated to have dapagliflozin each year from year 2023/24 <sup>5</sup>	10.0	9,000
<p><sup>1</sup> <a href="#">Quality and Outcomes Framework, Achievement, prevalence and exceptions data - 2017-18</a></p> <p><sup>2</sup> <a href="#">Diabetes UK</a></p> <p><sup>3</sup> <a href="#">National Diabetes Audit, 2016-17</a></p> <p><sup>4</sup> The <a href="#">diabetic retinopathy website</a> states that in type 1 diabetes, most people need a total of 0.5 - 0.8 units of insulin per kg of body weight/day. Therefore, it has been assumed that most people would likely have more than 0.5 units/kg of body weight/day</p> <p><sup>5</sup> Company submission rounded to 10% in model. All these people are assumed to have completed a structured education programme in line with the guideline recommendation.</p>		

## Assumptions

4.3 The resource impact template assumes that:

- The relevant comparator is optimised insulin therapy. However, clinical experts suggest that insulin is used by all patients in all treatment options with and without the dapagliflozin. Therefore, the cost of insulin has no impact on any switching of treatment choice and is set to zero in the model. The summary of product characteristics also states that insulin dose should not be reduced except to avoid hypoglycaemia.

- Insulin plus metformin has been included in the model. Clinical experts suggested that, in the UK, less than 10% of people with type 1 diabetes use metformin off-label. In the template we have used 5% in line with the company submission.
- People discontinuing dapagliflozin treatment do so at the end 6 months after starting and they revert to insulin only treatment.
- Drug costs exclude VAT because dapagliflozin is likely to be mainly prescribed in primary care. However, treatment is started and supervised by a consultant physician specialising in endocrinology and diabetes. Where dapagliflozin is prescribed in secondary care the template can be amended to include VAT.
- There are no additional monitoring costs associated with dapagliflozin. However, there may be additional costs related to increased blood glucose testing, additional ketone monitoring and visits to diabetes specialist teams associated with dapagliflozin.
- Administration costs are not included. It is assumed that the eligible population will already be being treated in a primary or secondary care setting as they do not have adequate glycaemic control despite optimal insulin therapy. However, there could be additional administration costs because dapagliflozin-treated patients may have extra visits to diabetic clinics, totaling one-hour of registrar time per year at a cost of £43 ([PSSRU 2018- Unit costs of Health and Social Care](#)).

### ***Sensitivity analysis***

- 4.4 A sensitivity analysis of key variables is included in the costing template. Key variables are detailed below.
- 4.5 Varying the percentage of people taking dapagliflozin from 5% to 15% results in a £3.4 million increase in resource impact from £1.7 million to £5.1 million.



4.6 Varying the percentage of people with type 1 diabetes 8% to 10% results in a £0.8 million increase in resource impact from £3.4 million to £4.2 million.

## About this resource impact report

This resource impact report accompanies the NICE guidance on [dapagliflozin with insulin for treating type 1 diabetes](#) and should be read with it.

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