

## North Staffordshire and Stoke-on-Trent Area Prescribing Committee

## Medicine Review Summary

## Faster Acting Insulin Aspart (Fiasp®) for treatment of diabetes

<b>Verdict:</b>	
<b>Formulary inclusion:</b>	Faster Acting Insulin Aspart (Fiasp®) is to be included in the North Staffs Joint Formulary
<b>Formulary category:</b>	Green
<b>Restrictions:</b>	For use only by practitioners experienced in the use of insulins Prescribe by brand
<b>Reason for inclusion:</b>	The committee was satisfied with the evidence that supports the safety and efficacy of Fiasp®. The speed of onset and duration of action allows flexibility in timing of mealtime insulin as it more closely mimics the normal human response to insulin; this may benefit some patient groups. Fiasp® is the same cost as Novorapid and therefore there are no cost implications associated with its use.
<b>Link to formulary:</b>	Stoke-on-Trent CCG website: <a href="https://www.stokeccg.nhs.uk/stoke-governance/policies/medicines-optimisation/joint-formulary">https://www.stokeccg.nhs.uk/stoke-governance/policies/medicines-optimisation/joint-formulary</a> North Staffordshire CCG website: <a href="https://www.northstaffscg.nhs.uk/governance/policies/medicines-optimisation/joint-formulary">https://www.northstaffscg.nhs.uk/governance/policies/medicines-optimisation/joint-formulary</a> Secondary care: Trust Intranet → Clinicians → Support services → Pharmacy → North Staffordshire Joint Formulary
<b>Link to medicine review summary:</b>	Stoke-on-Trent CCG website: <a href="https://www.stokeccg.nhs.uk/stoke-governance/policies/medicines-optimisation/formulary-review-and-verdict-sheets">https://www.stokeccg.nhs.uk/stoke-governance/policies/medicines-optimisation/formulary-review-and-verdict-sheets</a> North Staffordshire CCG website: <a href="https://www.northstaffscg.nhs.uk/governance/policies/medicines-optimisation/formulary-review-and-verdict-sheets">https://www.northstaffscg.nhs.uk/governance/policies/medicines-optimisation/formulary-review-and-verdict-sheets</a> Secondary care: Trust Intranet → Clinicians → Support services → Pharmacy → Joint Formulary Related Documentation → North Staffordshire & Stoke-on-Trent Area Prescribing Committee Medicine Review Summary Verdict Sheets
<b>Link to full review:</b>	Stoke-on-Trent CCG website: <a href="https://www.stokeccg.nhs.uk/stoke-governance/policies/medicines-optimisation/formulary-review-and-verdict-sheets">https://www.stokeccg.nhs.uk/stoke-governance/policies/medicines-optimisation/formulary-review-and-verdict-sheets</a> North Staffordshire CCG website: <a href="https://www.northstaffscg.nhs.uk/governance/policies/medicines-optimisation/formulary-review-and-verdict-sheets">https://www.northstaffscg.nhs.uk/governance/policies/medicines-optimisation/formulary-review-and-verdict-sheets</a> Secondary care: Trust Intranet → Clinicians → Support Services → Pharmacy → Joint Formulary Related Documentation → New Medicine Committee (NMC) Medicines Reviews

**Review summary:****Formulary Application:**

Fiasp®<sup>1</sup> was reviewed for inclusion in the North Staffordshire Joint Formulary for treatment of Type 1 and Type 2 Diabetes (T1DM and T2DM) in adults and pregnancy, where greater flexibility may be required in timing of dosing of mealtime insulin. Fiasp® time action profile mimics more closely, the normal human response to insulin than NovoRapid®<sup>2</sup> and is cost neutral compared to Novorapid®. Dr Sathiavageswaran (Consultant in Diabetes and Endocrinology) supported the application.

**Licensed indications:**<sup>1</sup>

Fiasp® is currently licenced for treatment of diabetes mellitus in adults

**Related Guidance:**

NICE Clinical Guideline<sup>3</sup>: <https://www.nice.org.uk/Guidance/NG17>

NICE Clinical Guideline<sup>4</sup>: <https://www.nice.org.uk/Guidance/NG28>

Scottish Medicines Consortium (SMC)<sup>5</sup>: <https://www.scottishmedicines.org.uk>

All Wales Medicines Strategy Group (AWMSG)<sup>6</sup>: <http://www.awmsg.org/awmsgonline>

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**Efficacy and safety:**<sup>7,8,9</sup>

The safety and clinical efficacy of Fiasp® has been investigated in 4 phase III RTC trials (Onset®1, Onset®2, Onset®3 and Onset® 4). Onset® 1 and 2 compared Fiasp® with NovoRapid® in patients with T1DM AND T2DM respectively. Onset® 3 and 4 provided supporting evidence to Onset® 1 and 2.

**Onset 1®:** Fiasp® effectively improved glycaemic control in adults with T1DM, showing a statistically significant greater reduction in HbA<sub>1c</sub> and superior Post-prandial plasma glucose (PPG) control when dosed with a meal compared to Novorapid®. There was no increase in risk of hypoglycaemia or weight gain with Fiasp®.

**Onset 2®:** Fiasp® effectively improved glycaemic control in adults with T2DM, showing non-inferiority to NovoRapid® in relation to change from baseline in HbA<sub>1c</sub>. There was a statistically significant benefit in 1 hour PPG control in patients treated with Fiasp® compared to Novorapid®.

**Onset 3®** showed Fiasp® plus basal insulin was superior to basal insulin plus metformin in effectively improving long term glycaemic control as measured by HbA<sub>1c</sub>.

**Onset 4®** showed change in baseline HbA<sub>1c</sub> over 6 weeks when both Fiasp® and NovoRapid® were given by Continuous Subcutaneous infusion (CSI), in comparison was not significant.

**Costs:****Current UHNM prices table for NMC review**

Medicine Description	Brand	Pack size	UHNS (incl. VAT)	Primary Care (exl. VAT)
FIASP 100units/1mL INJECTION (10mL)	INSULIN ASPART	1		£14.08
FIASP FLEXTOUCH 300units/3mL PREFILLED PEN	INSULIN ASPART	5		£30.60
FIASP PENFILL 300units/3mL CARTRIDGE	INSULIN ASPART	5		£28.31
NovoRAPID 100units/mL INJECTION (10mL)	INSULIN ASPART	1		£14.08
NovoRAPID FLEXPEN 300units/3mL PREFILLED PEN	INSULIN ASPART	5		£30.60
NovoRAPID FLEXTOUCH 300units/3mL PREFILLED PEN	INSULIN ASPART	5		£32.13
NovoRAPID 300units/3mL CARTRIDGE	INSULIN ASPART	5		£28.31
NovoRAPID PUMPCART 160units/1.6mL CARTRIDGE	INSULIN ASPART	5		£15.10
INSULIN HUMALOG 100units/1mL INJECTION (10mL)	INSULIN LISPRO	1		£16.61
INSULIN HUMALOG 300units/3mL CARTRIDGE	INSULIN LISPRO	5		£28.31
INSULIN HUMALOG 300units/3mL KWIK PEN	INSULIN LISPRO	5		£29.46
APIDRA 100units/1mL INJECTION (10mL)	INSULIN GLULISINE	1		£12.50
APIDRA 300units/3mL SOLOSTAR PEN	INSULIN GLULISINE	5		£28.30
APIDRA 300units/3mL CARTRIDGES	INSULIN GLULISINE	5		£22.50

**References:**

<sup>1</sup> Summary of Product Characteristics Fiasp® 100IU/ml solution for injection. Novo Nordisk Ltd 2017. Available at: <https://www.medicines.org.uk/emc/product/8109> (Accessed 5th December 2017)

<sup>2</sup> Summary of Product Characteristics NovoRapid® Flexpen 100IU/ml solution for injection. Novo Nordisk Ltd 2017. Available at: <https://www.medicines.org.uk/emc/product/7920> (Accessed 5th December 2017)

<sup>3</sup> National Institute for Health and Clinical Excellence (NICE) NG17. Type 1 Diabetes in adults: diagnosis and management. 2015. Available at <https://www.nice.org.uk/guidance/ng17>. (Accessed 11 December 2017)

<sup>4</sup> National Institute for Health and Clinical Excellence (NICE) NG28. Type 2 diabetes in adults: management. 2015. Available at <https://www.nice.org.uk/guidance/ng28> (Accessed 11 December 2017)

<sup>5</sup> Scottish Medicines Consortium. Insulin aspart (Fiasp®) 100 units/mL solution for injection in vial; solution for injection in cartridge (Penfill); solution for injection in pre-filled pen (FlexTouch). SMC No 1227/17. 2017. Available at <https://www.scottishmedicines.org.uk/>. (Accessed 10 December 2017)

<sup>6</sup> All Wales Medicines Strategy Group. Medicines excluded by AWMSG and for health board consideration of local formulary inclusion 2017. Available at <http://www.awmsg.org/awmsgonline/app/sitesearch?execution=e1s1>. (Accessed on 02/01/2018)

<sup>7</sup> Russell-Jones D, Bode B.E, et al: Fast-Acting Insulin Aspart Improves Glycemic Control in Basal-Bolus Treatment for Type 1 Diabetes (T1DM): Results of a 26 week, Multicentre, Active-Controlled, Treat-to-Target, Randomised, Parallel-Group Trial (Onset 1): Diabetes Care 2017; 40; 943 – 950

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<sup>8</sup> Bowering K, Case C, et al: Faster Aspart Versus Insulin Aspart As Part of a Basal-Bolus Regimen in Inadequately Controlled Type 2 Diabetes: The Onset 2 Trial: Diabetes Care 2017; 40; 951 - 957

<sup>9</sup> Rodbard H TS, Vidrio-Velaquez M, Tripathy D, Piletic D, Demissie M. Adding faster-acting insulin aspart to basal insulin significantly improved glycemic control: the Onset 3® trial. 76th annual Scientific Sessions of the American Diabetes Association (ADA); New Orleans, US 10-14 Jun 2016