Effective Shared Care Agreement (ESCA)

Fiasp® (insulin aspart)

ESCA: For use in pregnant women with either gestational diabetes or pre-existing diabetes, after other insulins have been tried and failed to reach post-prandial glucose targets

AREAS OF RESPONSIBILITY FOR THE SHARING OF CARE

This shared care agreement outlines suggested ways in which the responsibilities for managing the prescribing of Fiasp® can be shared between the specialist and general practitioner (GP). You are **invited** to participate however, if you do not feel confident to undertake this role, then you are under no obligation to do so. In such an event, the total clinical responsibility for the patient for the diagnosed condition remains with the specialist.

Sharing of care assumes communication between the specialist, GP and patient. The intention to share care will be explained to the patient by the specialist initiating treatment. It is important that patients are consulted about treatment and are in agreement with it. Patients with Diabetes in Pregnancy are usually under regular specialist follow-up, which provides an opportunity to discuss drug therapy.

The doctor who prescribes the medication legally assumes clinical responsibility for the drug and the consequences of its use.

RESPONSIBILITIES and ROLES

Specialist responsibilities
Confirm the pregnant women has gestational diabetes or pre-existing diabetes with a rise in post-prandial capillary blood glucose above the NICE recommended targets and are already on a rapid-acting analogue insulin (e.g. Novorapid®, Humalog®, Apidra®) as part of a basal-bolus insulin regime. NICE guidelines for Diabetes in Pregnancy recommends that pregnant women with any form of diabetes maintain their post-prandial capillary blood glucose below the following target level, without causing problematic hypoglycaemia: • 1 hour after meals: 7.8 mmol/litre or • 2 hours after meals: 6.4 mmol/litre. NICE also recommends that pregnant women with diabetes should aim to keep their HbA1c level below 48 mmol/mol (6.5%) Fiasp® will be recommended if pregnant women already on a rapid acting analogue have not achieved the targets above.
1. Discuss the potential benefits and treatment side effects with the patient
2. Ask the GP whether he or she is willing to participate in shared care before initiating therapy so that appropriate follow on prescribing arrangements can be made
3. Do baseline monitoring prior to initiation of Fiasp®
4. Ask GP to prescribe Fiasp® and discontinue other rapid acting insulin analogue
5. Review the patient's condition and monitor response to treatment regularly
6. A written summary to be sent promptly to the GP i.e. within 10 working days of a hospital outpatient review or inpatient stay
7. Fiasp® ▼is a black triangle drug. All suspected adverse effects should be reported to the MHRA https://yellowcard.mhra.gov.uk
8. Ensure clear backup arrangements exist for GPs, for advice and support (please complete contact details in appendix 1)

General Practitioner responsibilities						
1. Reply to the request for shared care as soon as practicable i.e. within 10 working days						
2. Prescribe Fiasp® at the dose recommended and discontinue other rapid-acting insulin						
3. Adjust the dose as advised by the specialist.						
4. In the patient's notes, using the appropriate read code listed below, denote that the patient is receiving treatment under a shared care agreement						
GP Prescribing System	**Read Code**	**Description**		**GP Prescribing System**	**Read Code**	**Description**
EMIS and Vision	8BM5.00	Shared care prescribing		SystmOne	XaB58	Shared care
5. Report to and seek advice from the specialist or clinical nurse specialist on any aspect of patient care that is of concern to the GP, patient or carer and may affect treatment						
6. Refer to specialist if concerns arise relating to Fiasp® use						
7. Report serious adverse events to specialist and MHRA via the Yellow Card Scheme https://yellowcard.mhra.gov.uk						
8. Stop treatment on advice of specialist						

Patient's role	
1.	Report to the specialist, clinical nurse specialist or GP if he or she does not have a clear understanding of the treatment
2.	Attend regularly for required blood tests and diabetes health checks. Patients are expected to maintain regular contact with their diabetes specialist team throughout their pregnancy, who will advise on Fiasp® monitoring
3.	Share any concerns in relation to treatment with Fiasp® with the specialist, clinical nurse specialist (CNS) or GP
4.	Report any adverse effects to the specialist, CNS or GP whilst taking Fiasp®
5.	Carry Fiasp® insulin passport with them to show healthcare staff
6.	Always check the insulin label before each injection to avoid accidental mix-ups between the different insulin aspart products.
7.	Regularly monitor own blood glucose levels, including after mealtimes, as advised by the specialist
8.	Attend regular outpatient appointments with the specialist
9.	Attend GP follow-up appointments

Please enter Specialist contact details and patient specific information in Appendix 1

SUPPORTING INFORMATION

Indication	Patients with diabetes in pregnancy who are experiencing a rise in post-prandial capillary blood glucose above the NICE recommended targets and are already on a rapid acting analogue insulin (e.g. Novorapid®, Humalog®, Apidra®) as part of a basal-bolus insulin regime. Fiasp® is licensed for use during pregnancy and breastfeeding.	
Dosage **Specialist to complete**		
Administration **Specialist to complete**	3 ml cartridge ☐ 3ml Pre-filled pen ☐ Fiasp® can be administered by subcutaneous injection up to 2 minutes before the start of the meal, with the option to administer up to 20 minutes after starting the meal. This may differ from other mealtime insulins	
Insulin passport **Specialist to complete**	Tick to confirm patient has been given a Fiasp® insulin passport ☐ Patient informed that Fiasp® will replace usual fast acting insulin ☐	
Contra-indications / Special precautions	**Presentations:** Fiasp® is available as Fiasp® 100units/ml solution 3ml pre-filled pen (FlexTouch), 3ml cartridge and 10ml vial. The dose in pre-filled pens can be dialled up in steps of 1 unit. The FlexTouch pen allows a dose of up to 80 units to be injected. **Avoidance of medication errors** There are two insulin aspart products currently on the market, which are NovoRapid® and Fiasp®. Other products may become available in the future. To avoid prescribing or administration errors: **Prescribers/Healthcare staff:** All prescriptions should specify the brand name of the insulin. Ensure patient has the correct insulin passport Discontinue other rapid-acting insulins when starting Fiasp® **Transfer from other insulin medicinal products** Switching between NovoRapid® or other insulins, and Fiasp® should only be done on the advice of the specialist diabetes team. Fiasp® is not directly interchangeable with other insulin aspart products.	
Side Effects	Very common	**Hypoglycaemia**: Omission of a meal or unplanned, strenuous physical exercise may lead to hypoglycaemia. Hypoglycaemia may occur if the insulin dose is too high in relation to the insulin requirement. Dose adjustment may be required in the case of hypoglycaemia or if hypoglycaemia is suspected. Due to the mode of action of Fiasp®, pregnant women initiated on Fiasp® may become more prone to hypoglycaemic events (capillary blood glucose < 4 mmol/litre) in the first 1-2 hours after meals. The specialist initiating Fiasp® should advise the patient regarding the adjustment of carbohydrate intake, safe management of hypoglycaemia and subsequent insulin doses. **Hyperglycaemia:** Inadequate dosing or discontinuation of treatment, especially in type 1 diabetes, may lead to hyperglycaemia and diabetic ketoacidosis
	Uncommon	**Eye disorder:** Intensification of insulin therapy with abrupt improvement in glycaemic control, may be associated with temporary worsening of diabetic retinopathy, while long-term improved glycaemic control decreases the risk of progression of diabetic retinopathy. Participation in retinopathy screening programmes is strongly advised. Please refer to SPC for full list- link under references

Monitoring	Pre-treatment assessment **Specialist to complete**	Date: Review of 2-weeks home blood capillary glucose monitoring showing 3 or more post prandial blood glucose readings above NICE-targets listed above
	After commencing treatment **Specialist to undertake**	Three-month review date:
	Discontinuation Criteria	No improvement in post-prandial capillary blood glucose levels. Increase in hypoglycaemic events attributed to initiation of initiation of Fiasp® Within first 3 months post-partum
	Actions following discontinuation **Specialist to undertake**	Replace with an alternative formulary rapid-acting insulin analogue Provide patient with updated insulin passport Communication to GP regarding insulin change

References

1. **SPC Fiasp www.medicines.org.uk. Accessed Feb 2019**
2. **Diabetes in pregnancy: management from preconception to the postnatal period. NG3. Aug 2015 www.nice.org.uk. Accessed Feb 2019**

Appendix 1:

Effective Shared Care Agreement (ESCA)

Fiasp®

For the treatment of Diabetes in Pregnancy

Please refer to BSSE APC formulary website for complete document.

BACK-UP ADVICE AND SUPPORT (To be completed by Specialist team)

Trust	Contact details	Telephone No.	Email address:
	Consultant:-		
	Specialist Nurse		

Patient's name	Date of birth	Sex	Home Address	Hospital Number
				NHS Number

Hospital Specialist/Consultant
Name (please print)_____Signature_____Date_____

To be completed by the General Practitioner:

I agree to participate in this shared care agreement for the treatment of the below named patient with *(drug name)* for *(indication)*

General Practitioner
Name (please print)_____Signature _____Date_____

Please keep a copy of this agreement for your own records and forward the original to the above named Consultant.

In the patient's notes, using the appropriate Read Code listed below, denote that the patient is receiving treatment under a shared care agreement.

GP Prescribing System	Read Code	Description		GP Prescribing System	Read Code	Description
EMIS and Vision	8BM5.00	Shared care prescribing		SystmOne	XaB58	Shared care