NHS BSW Process-Phase1: Switching from NovoRapid Flexpen to Trurapi SoloSTAR as the Preferred First-Line Rapid-Acting Analogue Insulin Therapy in Adults Aged Over 18 Years

Bath and North East Somerset, Swindon and Wiltshire Together

This process has been agreed with local specialist diabetes teams, who have confirmed that adult patients with Type 1 or Type 2 Diabetes Mellitus (T1DM or T2DM) may be switched in primary care where none of the exclusion criteria apply.

Purpose

To outline the steps for safely and effectively switching adult patients (over 18 years) from NovoRapid prefilled pens to Trurapi prefilled pens, in line with NHS BSW formulary guidance and cost-effectiveness principles.

Objectives

The following objectives aim to guide the effective adoption of Trurapi in clinical practice, ensuring value, consistency, and patient-centred care:

- Ensure patient safety during the switch.
- Maintain continuity of care.
- Communicate changes clearly to patients and carers.
- Reduce prescribing costs without compromising clinical outcomes.

Scope

This process outlines the recommended approach for prescribing Trurapi in primary care, focusing on appropriate patient groups and clinical considerations:

- Applies to adults (over 18 years) with Type 1 or Type 2 diabetes who are currently prescribed NovoRapid Prefilled pens 100units/ml
- Intended for prescribers working within primary care settings.
- Excludes patients with specific clinical needs, as detailed in the exclusion criteria.

Exclusion Criteria

Patients meeting any of the following criteria must not be switched from NovoRapid to Trurapi, to ensure safe, clinically appropriate prescribing and avoid potential risks

1. Age

- Patients under 18 years of age.

2. Pregnancy

- Patients who are currently pregnant or planning pregnancy.

3. Specialist Care or Complex needs

- Patients currently under the care of Haematology, Oncology, or Palliative services.
- Patients with complex clinical needs requiring individualised review prior to any treatment change

4. Patients Receiving Insulin via District Nurses

- These patients may have complex care arrangements and should be reviewed before any changes.

5. Insulin Delivery Method

- Patients using insulin pumps – Trurapi is not currently licensed for use with insulin pump therapy.

6. Allergy, Intolerance, or Previous Treatment Failure

- Patients with a known allergy or intolerance to Trurapi or its excipients.
- Patients who have previously failed a trial of Trurapi.

Implementation

To support a safe and effective transition to Trurapi, implementation will be delivered in two stages, each aligned to a clearly defined process to ensure consistency, clinical oversight, and appropriate patient engagement and education.

This process relates to Stage One and must be completed before progressing to Stage Two. Stage One focuses on patients currently prescribed **NovoRapid FlexPen pre-filled pens**, who will be prioritised for review and potential switch to Trurapi. This approach enables early impact on prescribing efficiency while maintaining patient safety and continuity of care.

Please refer to the process outlined below to guide each step of the transition. A process map for switching to **Trurapi SoloSTAR Pen** is provided in Appendix A.

1. Identification of Suitable Patients

- Import and run the SystmOne search provided. This search will identify all patients who currently have NovoRapid FlexPen pre-filled pens prescribed.
- If the lead diabetes team member is not conducting the search, the patient list should be shared with them to review and exclude anyone unsuitable for switching or needing additional support

2. Co-ordination with Community Pharmacists

- The Integrated Care Board (ICB) initiates engagement with Community Pharmacy through established communication channels with the Local Pharmaceutical Committee (LPC).
- Prior to initiating the proposed switch, engage with local pharmacies to inform them, review stock levels, and coordinate anticipated demand to support clear communication and consistent supply.

3. Patient Engagement

- Patient engagement must begin **before initiating the switch** from NovoRapid to Trurapi. This ensures patients are informed, supported, and able to ask questions or opt out if clinically appropriate.

- Materials should be provided in multiple formats (e.g., printed leaflets, digital guides, FAQs) to support understanding and accessibility. Address concerns and offer opt-out for exceptional cases. See Appendixes
- Engagement is led by individual practices, tailored to their patient population, resources, and clinical judgement.

4. Prescribing Information

- Trurapi is **not interchangeable** with Fiasp and should only be used where clinically appropriate. Fiasp may still be indicated in cases requiring a more rapid onset of action.
- Trurapi is a black triangle drug as it is relatively new to market. Suspected adverse reactions to Trurapi should be reported promptly via the Yellow Card Scheme. Yellow Card | Making medicines and medical devices safer
- Patients can be transferred from NovoRapid to Trurapi on a unit-for-unit basis, using their current NovoRapid® dose as a starting point.
- Patients using the NovoRapid FlexPen may transition directly to the Trurapi SoloSTAR pre-filled pen, which offers a similar delivery mechanism and user experience.
- Existing pen needles are compatible with pre-filled Trurapi pens, so no changes to needle prescriptions are required during the transition.

5. Managing the Transition

- Engage the patient before initiating the switch to ensure they are informed, supported, and given the opportunity to ask questions or opt out if clinically appropriate.
- Confirm compatibility by checking that the patient has suitable pen needles for Trurapi FlexPen.
- Update the repeat prescription in the clinical system to **Trurapi SoloSTAR** (pre-filled pen), ensuring it is prescribed by brand name to prevent errors from generic substitution.
- Verify prescription details, ensuring the correct strength, quantity, and alignment with previous dosing instructions.
- Document the change clearly in the patient's record, including counselling provided, insulin passport updates, and supply arrangements.
- Inform the patient that the change has taken place, reinforcing key information and support resources.

6. Monitoring and Follow-Up

- Patients should be advised to observe their blood glucose levels as usual and to contact their clinical team if they notice any changes or concerns in their readings.
- A follow-up appointment should be arranged if the patient has any concerns after the switch. This allows for early support and reassurance.
- During the next scheduled review, assess how well the new treatment is working and address any issues.
- Trurapi is a black triangle drug as it is relatively new to market. Suspected adverse reactions to Trurapi should be reported promptly via the Yellow Card Scheme. Yellow Card | Making medicines and medical devices safer

Governance and Audit

- Record all medication switches, including rationale and clinical justification.
- Document all patient discussions regarding medication changes, ensuring informed consent and shared decision-making are clearly noted.
- Maintain a central log or database for tracking switches and patient
- Quantify and report cost savings resulting from prescribing changes.

Further Information

Please see Appendices for supportive templates to facilitate switch programmes. These can be adapted as necessary

Resources for Health Care Professionals

Trurapi 100 units/ml solution for injection in pre-filled pen - Summary of Product Characteristics (SmPC) - (emc) | 12738

TRURAPI® ▼ (INSULIN ASPART 100 UNITS/ML) (GB ONLY)

Resources For Patients

Trurapi® ▼ | Sanofi Diabetes Patients Website

Switching to Biosimilars | The Patients Association

Trurapi SoloStar Guide.pdf

Trurapi SoloStar Pen Digital Passport Q2 2021.pdf

REFERENCES

- Guidance on the licensing of biosimilar products - GOV.UK
- Overview | Type 1 diabetes in adults: diagnosis and management | Guidance | NICE
- Overview | Type 2 diabetes in adults: management | Guidance | NICE
- TRURAPI® ▼ (INSULIN ASPART 100 UNITS/ML) (GB ONLY)
- NHS England » National medicines optimisation opportunities 2024/25
- Statement-scientific-rationale-supporting-interchangeability-biosimilar-medicines - EMA review following PROM endorsement

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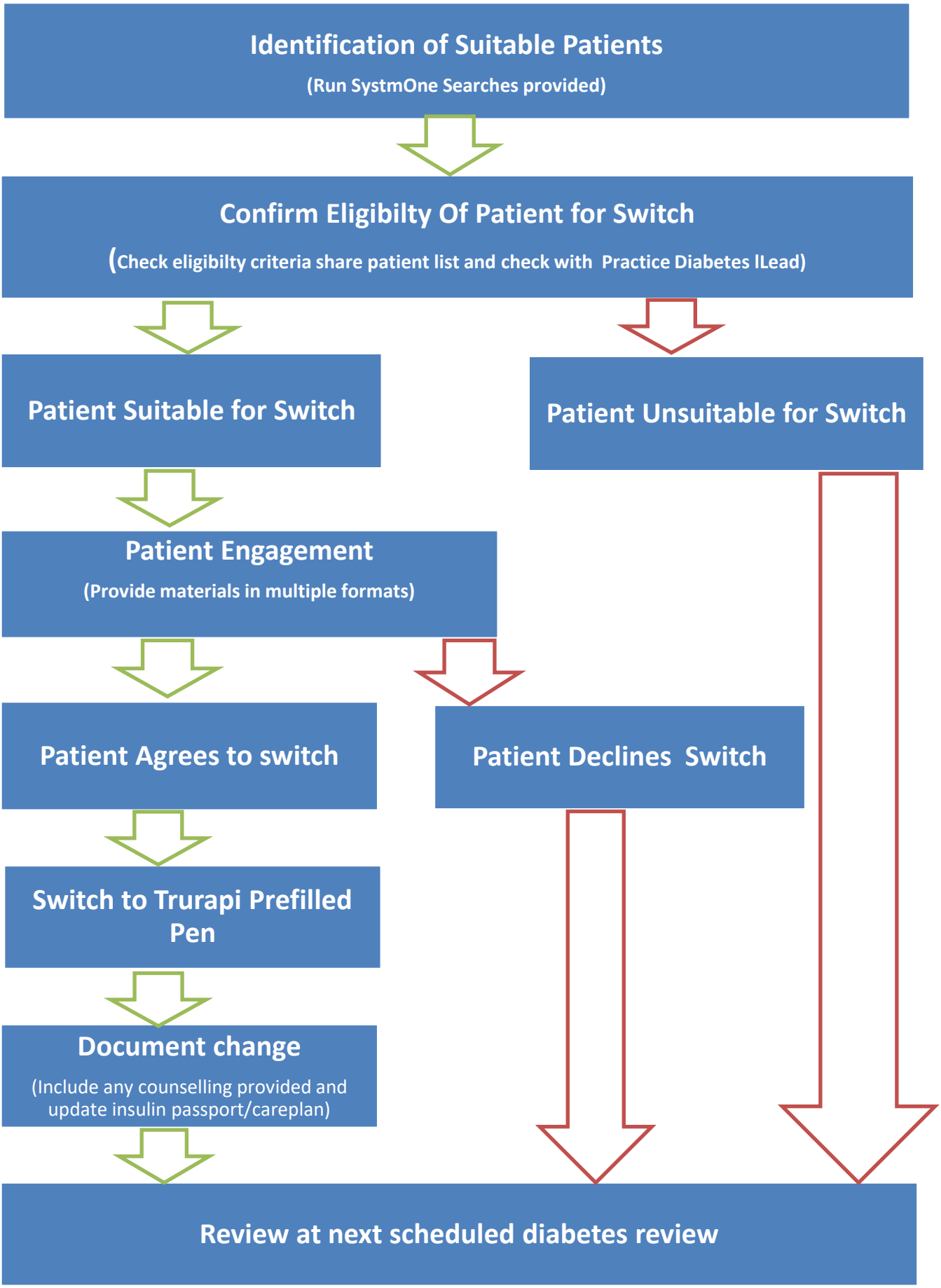
Appendix A: Process Map For Trurapi Prefilled Pens 100units/ml



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APPENDIX B: FAQS for Biosimilars

Insulin aspart and biosimilars

Trurapi, the new insulin aspart

This leaflet offers more information about a new form of insulin aspart, a quick acting form of insulin used at mealtimes, called Trurapi.

Why am I receiving this leaflet?

You are currently receiving treatment with NovoRapid in a Flexpen device. NovoRapid is the name given by the drug company to its product insulin aspart. Once a new drug has been developed and introduced there are laws that protect copy drugs from being used for a certain length of time. This is called its patent. The patent for NovoRapid has now expired and so other forms of insulin aspart are now licenced and available for use. These newer versions of biologic drugs are called biosimilars.

What is a biosimilar?

The World Health Organization (WHO) has defined a biosimilar as **a drug that is similar in terms of quality, safety and efficacy (effectiveness) to the original licensed biological product**. This means that biosimilars are only allowed to have minor differences from the original licensed biological product. Any small differences must not alter how well the drug works, how safe it is, or how the drug reacts with the body's immune system. Biosimilars are regulated in a very similar way to the original licensed product.

The Medicines and Healthcare products Regulatory Agency (MHRA) has approved the use of Trurapi as new version (biosimilar) of insulin aspart, and it has been shown to be as safe and as effective as NovoRapid.

Because biosimilar drugs offer cost savings and enable us to deliver care more effectively, we are aiming to switch patients currently using **NovoRapid** (insulin aspart) over to **Trurapi** (the biosimilar version of insulin aspart). This practice is supported by latest NICE guidance in management of diabetes.

What does this mean for me?

Because NovoRapid and Trurapi contain the same active product (Insulin Aspart), treatment for your diabetes remains unchanged. The pre-filled pen (Solostar) is similar to the Flexpen and is identical to delivery device for other commonly used insulins, including Lantus. The same pen needles will fit to the pen.

As a precaution you should monitor your blood glucose to ensure this is the case.

What if I have further questions?

We are aware that some patients may have more questions than others about Trurapi. Some other patients would prefer to chat to someone on a face-to-face basis or on the phone. Your practice pharmacist or usual diabetes educator/clinician can provide information on Trurapi.

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APPENDIX C: Template letter for switching from NovoRapid FlexPen to Trurapi SoloSTAR Pen

Dear Patient

IMPORTANT INFORMATION ABOUT YOUR REPEAT PRESCRIPTION

Change in brand of your short acting insulin from Novorapid® to Trurapi®

We are writing to you as you are using short acting insulin aspart (also known as Novorapid®) to manage your diabetes.

The NHS now has another brand of insulin aspart available to prescribe called Trurapi. Trurapi is a biosimilar version of the insulin aspart contained in your current Novorapid®. It has been tested to ensure that it is equally effective and safe.

As you know, the NHS is under great financial pressure and it is extremely important that we make sure we spend public money carefully, using the better value choices, so that the NHS can afford the best care for patients. **Trurapi is much better value for the NHS to prescribe.** Local diabetes experts have agreed that patients who are currently being treated with Novorapid should be switched to Trurapi.

To help us achieve that goal, we are switching all patients who are prescribed NovoRapid Flexpen 100units/ml solution for injection 3ml pre-filled pen to Trurapi 100units/ml solution for injection 3ml pre-filled Solostar pen,

Your Insulin will change from

Novorapid® Flexpen Prefilled Pens

To

Trurapi® SoloSTAR Prefilled Pens

There will be no need to change your dose, and this will not have any negative impact on your diabetes control. You should **continue to administer your current dose and in the same way**

Before you are due to run out of your Novorapid® insulin please:

Prepare for using your new insulin by watching a demonstration of how to use the new Trurapi® Solostar pen device at: https://www.mysanofiinsulin.co.uk/Trurapi®/

If you don't have access to the internet, you can find instructions inside the packaging of your new Trurapi® insulin, so please order this in good time before you are due to run out of your existing insulin. If you have any questions about how to use the pen, then please contact the diabetes team or your practice nurse.

Unless we hear from you to discuss any concerns, your next supply of insulin will be Trurapi.

We do not anticipate that you will experience any problems with your new medicine. Please continue to monitor your blood glucose at home in the usual way.

If you have any queries please speak to your GP, nurse, practice pharmacist or diabetes team. As with all medicines please read the patient information leaflet for your new medicine.

Yours Sincerely