



**This position 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.**

## Position Statement

The Area Prescribing Group recommends Trurapi as the preferred first-line choice Rapid Acting Analogue Insulin when prescribing insulin aspart. In line with this recommendation:

- All new patients over 18 years of age requiring insulin aspart should be initiated on Trurapi, where clinically appropriate for the individual.
- Opportunistic and planned switches from NovoRapid to Trurapi should be conducted in both primary care and secondary settings, ensuring that patients meet the inclusion criteria and no exclusions apply.
- Fiasp is **not** interchangeable with Trurapi and should only be considered for patients who require a significantly faster onset of action than standard rapid-acting insulin analogues. Patients already established on Fiasp should remain on it unless a clinical review supports a change.

This approach supports cost-effective prescribing while maintaining clinical safety and efficacy and aligns with regional and national prescribing priorities.

## Background

Biosimilars are biological medicines highly similar to their reference products, with no clinically meaningful differences in terms of safety, efficacy, or quality. They are rigorously evaluated through comparability exercises and have been used in the UK since 2006. For the NHS, biosimilars offer a valuable way to reduce costs—especially in treating long-term conditions such as diabetes.

Trurapi, a biosimilar of NovoRapid, is manufactured by Sanofi and indicated for the treatment of diabetes mellitus in adults. It demonstrates comparable pharmacokinetics, pharmacodynamics, safety, and glycaemic control to NovoRapid, supported by clinical trial and real-world data.

Key findings include:

- Equivalent HbA1c reduction in both Type 1 and Type 2 diabetes.
- Similar fasting and postprandial glucose profiles.
- Comparable incidence of hypoglycaemia and immunogenicity.

Trurapi has already been successfully used across many areas in England, with patients safely switched from NovoRapid.

## Rationale

- Trurapi offers notable cost savings, with NHS list prices around 30% lower for pens and cartridges, and 15% lower for vials—making it a more affordable option for insulin therapy.
- NICE guidelines (NG17 and NG28) encourage prescribing the insulin with the lowest acquisition cost, which supports the use of biosimilars like Trurapi without compromising clinical effectiveness.
- The use of Trurapi aligns with NHS England's medicines optimisation objectives, particularly the focus on using best-value biological medicines to improve system-wide efficiency.



## Objectives

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

- Position Trurapi as the preferred insulin aspart for patients starting rapid acting insulin therapy, ensuring consistency with cost-effective prescribing practices.
- Support both opportunistic and planned switches from NovoRapid to Trurapi, helping to maximise value while maintaining clinical confidence.
- Maintain a strong focus on clinical safety, patient engagement, and continuity of care throughout the transition process.

**Note: Currently 'Stage 1' of switching will ONLY focus on switching from NovoRapid FlexPen prefilled pens to Trurapi Solostar prefilled pens. See detailed 'Implementation' section below.**

## Scope

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

- Applies to adults with Type 1 or Type 2 diabetes who are currently prescribed NovoRapid.
- 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.

- **Age**
  - Patients under 18 years of age.
- **Pregnancy**
  - Patients who are currently pregnant or planning pregnancy.
- **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.
- **Patients Receiving Insulin via District Nurses**
  - These patients may have complex care arrangements and should be reviewed before any changes.
- **Insulin Delivery Method**
  - Patients using insulin pumps – Trurapi is not currently licensed for use with insulin pump therapy.
- **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.

- Device Requirements
  - Patients requiring the functionality of a smart durable pen (e.g. NovoPen 6 or NovoPen Echo Plus), such as electronic recording of doses and administrations.

## Prescribing Information

To ensure safe and accurate prescribing of Trurapi, the following guidance should be followed when initiating or switching treatment:

- Trurapi is **not** interchangeable with Fiasp. Patients who require a substantially faster onset of action than standard rapid-acting insulin analogues should remain on Fiasp unless a clinical review determines that a change is appropriate.
- 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](#)
- Always prescribe by brand name—**Trurapi**—to avoid errors due to generic substitution.
- Patients can be transferred from NovoRapid to Trurapi on a unit-for-unit basis, using their current NovoRapid dose as a starting point.
- 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.
- Patients using the NovoRapid FlexPen may transition directly to the Trurapi SoloSTAR pre-filled pen, which offers a similar delivery mechanism and user experience.
- Trurapi is also available in cartridge form for patients using NovoRapid Penfill cartridges. These are compatible with Sanofi reusable pens, including the JuniorSTAR (half-unit dosing, starting from 1-unit) and AllStar PRO (single-unit dosing). Note: Trurapi cartridges are not compatible with Novo Nordisk pen devices.
- Sanofi pen devices do not support smart functionality. Patients relying on digital features such as dose tracking with NovoPen 6 or NovoPen Echo should not be switched to Trurapi.
- Existing pen needles are compatible with both reusable and pre-filled Trurapi pens, so no changes to needle prescriptions are required during the transition.

## Implementation

To support a safe and effective transition to Trurapi, the switch will be delivered in **two distinct stages**, and **Stage 2 will only begin once Stage 1 is fully completed**. Each stage follows a defined process to ensure consistency, clinical oversight, and appropriate patient engagement and education.

- **Stage 1: Prefilled Pens (NovoRapid FlexPen)**  
Patients currently prescribed NovoRapid FlexPen prefilled pens will be prioritised for review and potential switch to **Trurapi SoloSTAR prefilled pens**. This stage enables early impact on prescribing efficiency while maintaining continuity of care.



- **Stage 2: Cartridges (NovoRapid Penfill)**

Once Stage 1 is complete; the focus will shift to patients using NovoRapid cartridges. As this phase involves a change in delivery device, additional support and training may be required to ensure patients are confident with the new pen and any education needs are addressed.

Please refer to the detailed processes outlined in the supporting documents for guidance on each stage of the transition. One document provides guidance for the switch to **Trurapi SoloSTAR (prefilled pens)**, and the other focuses on the switch to **Trurapi Solution for injection cartridges**. Each includes a step-by-step process and an accompanying process map to ensure consistency and safe implementation.

## 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.

## References

- [Trurapi 100 units/ml solution for injection in pre-filled pen - Summary of Product Characteristics \(SmPC\) - \(emc\) | 12738](#)
- [Trurapi 100 units/ml solution for injection in cartridge - Summary of Product Characteristics \(SmPC\) - \(emc\) | 12737](#)
- [TRURAPI® ▼ \(INSULIN ASPART 100 UNITS/ML\) \(GB ONLY\)](#)
- [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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