Therapeutics Advisory Group

Improving lives together
Norfolk and Waveney Integrated Care System

TRURAPI® (biosimilar insulin aspart)
Preferred first-line choice when prescribing insulin aspart

Norfolk and Waveney TAG recommends Trurapi® (biosimilar insulin aspart) as the preferred first-line choice when prescribing insulin aspart.

ADVICE - Treatment can be initiated in primary care following advice or recommendation from clinician in primary or secondary care with relevant expertise

Norfolk and Waveney TAG recommends Trurapi® (biosimilar insulin aspart) as the preferred first-line choice when prescribing insulin aspart and that:

- **All new patients requiring insulin aspart should be initiated on Trurapi® provided this is appropriate for the individual patient.**
- **Opportunistic and managed switches from NovoRapid® to Trurapi® should be undertaken in primary and secondary care, unless there is a clinical reason that an individual patient should not be switched.**

Background

Biosimilars are considered therapeutically equivalent and interchangeable with their reference product[1,2,3,7] and it is likely that their availability and use will become more widespread over the next few years. Biosimilars have the potential to offer the NHS considerable cost savings, especially as they are often used to treat long term conditions. Trurapi® (biosimilar insulin aspart) demonstrates similar pharmacokinetics, has been shown to be non-inferior in terms of glycaemic control, and has a similar safety and immunogenicity profile to the reference product (NovoRapid®), in both type 1 and type 2 diabetes [8].

There is no scientific rationale to expect different clinical outcomes when switching between biosimilars of the same reference product and this is supported by real-world data[2]. Patients have been safely switched from NovoRapid® to Trurapi® in many areas across England.

Rationale

The NHS list price of Trurapi® pre-filled pens and cartridges is approximately 30% less, and the vials approximately 15% less than NovoRapid®. Based on current expenditure across NHS Norfolk and Waveney ICB, switching 80% of patients from NovoRapid® to Trurapi® would save approximately £340,000 per annum. The use of best value biological medicines is one of 16 national medicines optimisation priorities identified by NHS England[8].

Prescribing information[2,3]

- All insulin prescriptions should include the brand name, the strength of the insulin and the administration device to ensure continuity of supply.
- **Pre-filled Pen** - The Trurapi® pre-filled pen device is a SoloStar® pen, which is the same one used for all other Sanofi insulins.
- **Cartridges** - Trurapi® cartridges should only be used with JuniorSTAR® pens (capable of half-unit dosing), and Tactipen®, AllStar® or AllStar PRO® pens (which all deliver insulin in single unit increments). If prescribing Trurapi® cartridges, **an appropriate durable pen will also need to be supplied with the initial prescription.** Trurapi® cartridges are not compatible with Novo Nordisk durable pens.

- Transferring a patient from NovoRapid® to Trurapi® can initially be done **unit-for-unit** based on the existing NovoRapid® dose. Further dose adjustments may be required based on blood glucose readings.
- Trurapi® is a black triangle drug as it is relatively new to market and is subject to additional monitoring. This will allow quick identification of new safety information. Healthcare professionals are asked to report any suspected adverse reactions via Yellow Card Scheme at: www.mhra.gov.uk/yellowcard or search for MHRA Yellow Card in the Google Play or Apple App Store.
- Trurapi® is NOT considered interchangeable with Fiasp®, which can still be used where indicated (e.g., when a more rapid onset of action is required).

Implementation plan

- Communication of the Norfolk and Waveney Trurapi® position statement to be undertaken by medicines optimisation team and shared for dissemination with system partners by Trust pharmacy teams, clinical networks and Local Pharmaceutical Committee.
- Communication to be sent to all healthcare professionals involved in the care, including the supply of insulin, of patients with diabetes.
- If clinically appropriate and in line with the switching guidance, patients can be switched from NovoRapid® to Trurapi® opportunistically or as part of planned care. This can be carried out at annual review with specialist within Acute or Community Trust, or by GP practice.
- Acute Trusts, Community Trusts and GP practices will switch/facilitate the switch of existing patients in primary care on NovoRapid® to Trurapi® with appropriate counselling where this is clinically appropriate and in line with the detailed switching guidance. All new patients requiring Insulin aspart and where clinically appropriate, will be initiated on Trurapi®.

An information pack has been produced to support the implemetnation and switching of Trurapi in clinically appropriate patients. Please see Appendix 1

Costs

Insulin Aspart 100units/ml solution for injection	Pack Size	NHS price[7] (June 2025)
NovoRapid® 100units/ml 3ml cartridges	5 x 3ml Cartridges	£28.31
Trurapi® 100units/ml 3ml cartridges	5 x 3ml Cartridges	£19.82
NovoRapid® 100units/ml 3ml pre-filled FlexPen pens	5 x 3ml Pens	£30.60
Trurapi® 100units/ml 3ml pre-filled Solostar pens	5 x 3ml Pens	£21.42
NovoRapid® 100units/ml 10ml vials	1 x 10ml Vials	£14.08
Trurapi® 100units/ml 10ml vials	1 x 10ml vials	£11.97

Further information

Resources for healthcare professionals:

Trurapi® summary of product characteristics

Sanofi campus - Trurapi®

Resources for patients:

Sanofi diabetes patient website - Trurapi®

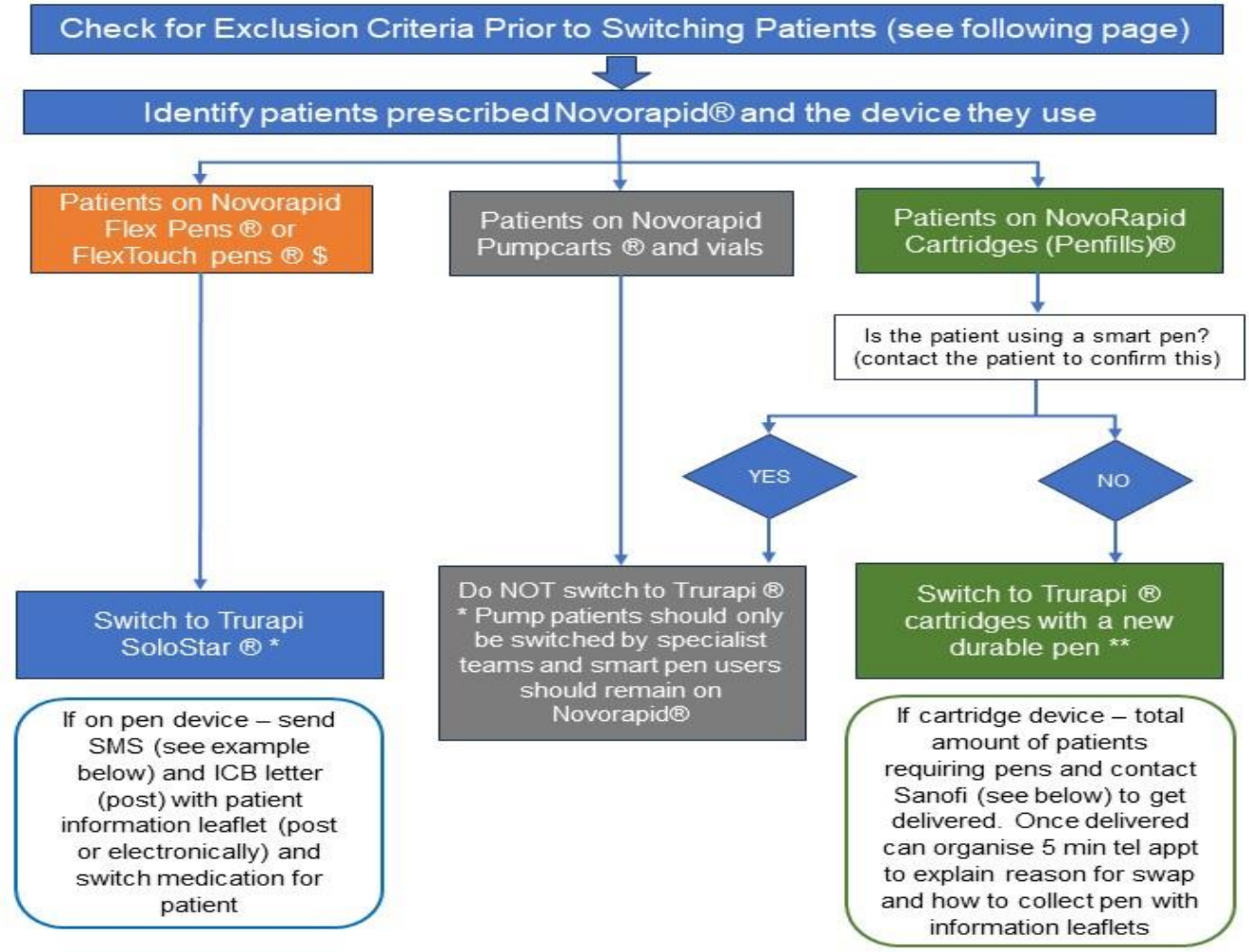
https://www.patientsassociation.org.uk/switchingtobiosimilar

References

1. Medicines and Healthcare Products Regulatory Agency. Guidance on the licensing of biosimilar products. Last updated 7 November 2022 [accessed 27 September 2024].
2. European Medicines Agency. Statement on the scientific rationale supporting interchangeability of biosimilar medicines in the EU. Last updated 21 April 2023 [accessed 27 September 2024].
3. NHS England. What is a biosimilar medicine? Last updated 21 February 2023. [accessed 07 June 2022].
4. SPS. Understanding biological and biosimilar medicines. Last updated December 2023 [Accessed 25 October 2024]
5. NHS England. *National medicines optimisation opportunities 2024/25* Last updated September 2024 [Accessed 25 October 2024].
6. NHS England. Commissioning framework for biological medicines (including biosimilar medicines). Published September 2017. [Accessed 25 October 2024]
7. NHS Business Services Authority. Dictionary of medicines and devices (dm+d). [accessed 24 June 2025].
8. Sanofi Campus. Trurapi. Last updated April 2024 [accessed 24 June 2025]

APPENDIX 1: Switching patients on NovoRapid® to Trurapi®

Why? – support cost saving for N&W ICB and ensuring patient has appropriate medication in line with formulary guidance.
How? – through relevant clinical system search and use of pre-prepared guidance and letters to support practices.



***Trurapi® Solostar**	When switching patients to Trurapi SoloStar®, the patient should be informed, and a prescription issued. It would be good practice to include the phrase **"This is equivalent to NovoRapid®"** on the initial prescription for reassurance.
****** **Trurapi® Cartridges**	When switching patients to Trurapi cartridges®, the patient should be informed, and a prescription issued. It would be good practice to include the phrase **"This is equivalent to NovoRapid®"** on the initial prescription for reassurance. Patients prescribed **Trurapi® cartridges** will also need to be supplied with two durable pen devices, noting that: (1) If using whole units then they should be offered TWO AllStar PRO® pens; (2) If using half units then they should be offered TWO JuniorSTAR® pens; (3) The durable pen device they are given should be a **different colour** to the insulin pen they use for their longacting insulin (AllStar PRO® pens are available in blue and silver and JuniorSTAR® pens are available in blue, red and silver). AllStar Pro® Pen leaflet link - https://www.mysanofiinsulin.co.uk/lantus/downloads/Lantus/allstar-pro-patient-booklet-2023.pdf

Contact Sanofi for supplies of Sanofi durable pens and patient information leaflets.

$ **NovoRapid FlexTouch® pens are being discontinued in March 2025 and there are no alternative devices for patients with reduced dexterity.**
Patients can **continue to use their current insulin needles** which are compatible with Sanofi product.

Considerations for converting existing patients to Trurapi®
Patient can initially be switched from NovoRapid® to Trurapi® **unit-for-unit** based on the previous NovoRapid® dose (i.e., initial Trurapi dose = existing NovoRapid® dose)[8]. Patients should continue to monitor their blood glucose as usual and can continue to use their current insulin needles.

Note the following exclusion criteria for switching patients.
The following patient cohorts must NOT be switched from NovoRapid® to Trurapi®

- Patients requiring the functionality offered by a smart durable pen (e.g. NovoPen 6® / NovoPen Echo Plus®) such as electronic recording of doses and administrations;
- Patients prescribed a NovoRapid PumpCart® or NovoRapid® vials should only be switched by specialist diabetes teams if appropriate. They may also be prescribed back-up NovoRapid FlexPens® and cartridges for use in the event of pump failure, these should also only be switched by specialist diabetes teams;
- Patients prescribed NovoMix® (biphasic insulin aspart / insulin aspart with insulin aspart protamine) as this is NOT the same as NovoRapid®;
- Patients who have had a previous trial of Trurapi® or have recorded allergy to it, or any of the excipients;
- Patients on the Fiasp® brand of insulin aspart as this is NOT considered interchangeable with Trurapi®;

Additional precautions should be taken before switching the following cohorts from NovoRapid® to Trurapi®

- NovoRapid FlexTouch® pen devices have a non-extending dose button requiring a lower injection force than traditional disposable pens and therefore may be more suitable for certain patients, e.g., those with dexterity issues. Confirm before switching whether the FlexTouch® functionality is required.
- Patients with cognitive impairment, dementia or a learning disability who self-administer their insulin should be assessed individually to ascertain appropriateness before switching to Trurapi®.
- Pregnant patients currently prescribed NovoRapid® should NOT be switched until post-partum. For treatment of new diabetes diagnosis during pregnancy Trurapi® is the first line insulin aspart if required.

Resources:
Available via Sanofi website for use to support patients:

- Trurapi patient information leaflet: https://www.mysanofiinsulin.co.uk/trurapi/downloads/Trurapi/Your%20Guide%20to%20Trurapi%20-%20Patient%20Booklet%20Q4%202021.pdf
- Step-by-step guide for patients using pre-filled pen: https://www.mysanofiinsulin.co.uk/trurapi/downloads/Trurapi/Trurapi_SoloStar_Guide.pdf
- Pre-filled pen insulin passport: https://www.mysanofiinsulin.co.uk/trurapi/downloads/Trurapi/Trurapi%20SoloStar%20Pen%20Digital%20Passport%20Q2%202021.pdf
- Cartridges insulin passport: https://www.mysanofiinsulin.co.uk/trurapi/downloads/Trurapi/Trurapi%20Cartridges%20Digital%20Passport%20Q2%202021.pdf

SMS Template Example:

Example SMS that can be sent to patients on pen devices without need for appointment:

'Hello - this is a message to say that we are swapping your Novorapid pen to a new pen called 'Trurapi' on your repeats. This is a biosimilar medication used to help with cost-effectiveness and availability. The dosage will not change and the insulin will work in exactly the same way. You will shortly receive information in the post regarding this. Thank you. The XXX Team'

Patient information leaflet:

Patient information leaflet that can also be sent or given to each patient either electronically or by post – NHS England 2023 *What is a biosimilar medication?* And/or Sanofi *guide to Trurapi.*

https://www.england.nhs.uk/long-read/what-is-a-biosimilar-medicine/

https://www.mysanofiinsulin.co.uk/trurapi/

Practice Example Response to Biosimilar Queries:

If a patient has queries regarding the biosimilar, please see statement below to support your discussion:

You have been issued a biosimilar insulin which is a new version of an existing insulin product made by a different company. It is essentially the same and has been extensively tested to ensure that it has the same effects and that it is as safe as the original product. Biosimilar insulins are much more cost effective than the original products for the NHS but won't negatively impact on your diabetes control. For more information about biosimilar medicines, visit https://www.patients-association.org.uk/switchingtobiosimilars

The safety of these medications are required by law to be reviewed centrally through the European Medicines Agency. Once authorised, biosimilars are subject to the same level of post-authorisation regulatory scrutiny as the current medication you are given. As they have essential aspects similar to your current medication, **this results in a like-for-like use** meaning no change is required to your insulin dosage.

Biological medicines are currently the largest cost and cost growth areas in the NHS medicines budget. Through making biosimilar medicines more quickly available the NHS will be able to take advantage of savings each year offered by these new products, enabling more patients to have access to other lifesaving and life-enhancing treatments.

Reference: Sanofi (2022) *What are biosimilar medicines?* Available at: https://www.campus.sanofi/dam/jcr:bb511738-7a71-417f-afcb-d70d669be4fe/biosimilar-summary.pdf.

FAQs:

1. **What support is available for the practice?**
   Each practice can access their ICB for information and guidance from the medicines optimisation and diabetes clinical team alongside specialised guidance to support their practice. Additionally, Sanofi provide good overviews of biosimilar medications and the local representative is also available for information as required.

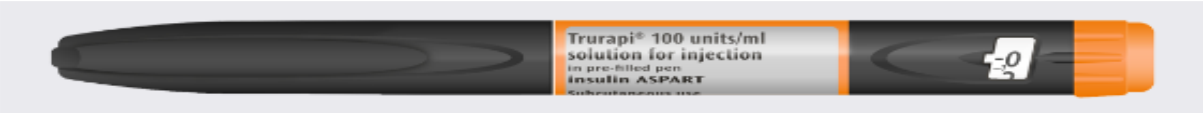
2. **What about if a patient does not want to change their medication?**
   We are aware patients may be concerned about change their medication, however we would advise reassuring patients that the specialist services are happy and aware this is taking place alongside the practice example response to highlight to patients the reasons why this is taking place. If a patient subsequently refuses after discussion with a clinician and reviewing the relevant medications, this needs to be documented clearly.

3. **How long does the process take and what is expected of Primary Care?**
   We understand that primary care is facing extreme pressures at present, but by utilising the information provided this should take no more than 1 session (that being on average up to 4 hours) to complete depending on your population size. For those using cartridges a new pen device will be required that can be supplied by Sanofi for patient use. The guides provided should

help structure your planning and allow you to utilise the biosimilars in a safe and effective practice to support best value patient care.

4. **How long does the process take and what is expected of Secondary Care?**
We understand that during the patient's specialist review there may be an opportunity to switch to Trurapi. The information provided can be used to support the change. All new patients requiring insulin aspart should be initiated on Trurapi® provided this is appropriate for the individual patient.
Primary care should be made aware of the initiation/ change using the normal channels of communication and will continue prescribing according to the specialist advice. For those using cartridges a new pen device will be required that can be supplied by Sanofi for patient use. The guides provided should allow you to utilise the biosimilars in a safe and effective practice to support best value patient care.

What do Trurapi SoloStar® devices look like? Trurapi SoloStar® devices are prefilled, disposable pens similar in appears to Sanofi's other insulins (like Lantus®) but they are orange in colour. A picture of the Trurapi SoloStar® pen is shown below.



What do Trurapi® cartridges and AllStar PRO® pen devices look like? Trurapi® cartridges are similar to NovoRapid® cartridges in appearance but are NOT compatible with Novo Nordisk® durable pens. Trurapi® cartridges should only be used with Sanofi durable pens (such as AllStar PRO® and JuniorSTAR® pens). A picture of the cartridge and the AllStar PRO® durable pen device is shown below.

Title	TRURAPI® (biosimilar insulin aspart) Preferred first-line choice when prescribing insulin aspart
Description of policy	*To inform healthcare professionals*
Scope	*Norfolk and Waveney Integrated Care System*
Prepared by	Norfolk and Waveney ICB Medicines Optimisation Team
Impact Assessment (Equalities and Environmental)	*Please indicate impact assessment outcome:* *Positive impact* *Adverse impact - low - action plan completed as per guidance* *Adverse impact - medium - action plan completed as per guidance* *Adverse impact - high - action plan completed as per guidance* *No impact* ***No policy will be approved without a completed equality impact assessment***
Other relevant approved documents	
Evidence base / Legislation	Level of Evidence: *A. based on national research-based evidence and is considered best evidence* ***B. mix of national and local consensus*** *C. based on local good practice and consensus in the absence of national research based information.*
Dissemination	Is there any reason why any part of this document should not be available on the public web site? ☐ Yes / No ☒
Approved by	*Norfolk & Waveney Therapeutics Advisory Group (TAG) (July 2025)*
Authorised by	*Medicines Optimisation Programme Board on behalf of the ICS (July 2025)*
Review date and by whom	Medicines Optimisation Team – July 2027
Date of issue	July 2025

Version Number	Author	Purpose / Change	Date
1.0	Medicines Optimisation Team	To support prescribing	July 2025