Rationale for Initiation, Continuation and Discontinuation (RICaD)

# Toujeo® (Insulin glargine) 300units/mL
# For the treatment of patients with Type 1 or Type 2 diabetes who have nocturnal hypoglycaemia and are on ≥80 units of basal analogue insulin (e.g. Abasaglar®, Lantus®, Levemir® or Semglee®)

This document supports the use and transfer of an agent which is classified as **AMBER**.
It is intended for completion by specialists in order to give Primary Care prescribers a clear indication of the reason for recommending an **AMBER** medication together with suggested criteria for its subsequent continuation or discontinuation. This RICaD should be provided as a supplement to the specialist's clinical letter.

| **Patient details** | | **GP details** | | **Specialist details** | |
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| **Name** | | **GP Name** | **Dr** | **Specialist Name** | |
| **NHS Number** | | **GP address** | | **I confirm that this patient is eligible to receive Toujeo® 300units/mL under the restrictions listed below** | |
| **DOB** | | | | **Signature** | |
| **Patient address** | | | | **Date** | |
| | | | | **Contact details** | |

**Rationale for Choice**

| **Specialist to complete** | |
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| Relevant Diagnosis: | This RICaD only supports the prescribing of Toujeo® insulin **300 units/mL** for patients with Type 1 or Type 2 diabetes in line with the indications below. |
| Agreed Indication for inclusion in the BSSE APC Formulary: | **Nocturnal hypoglycaemia AND already taking ≥80 units of basal analogue insulin (e.g Abasaglar®, Lantus®, Levemir® or Semglee®)**<br>Transfer to Primary Care should not happen until specialists can demonstrate reduction in nocturnal hypos (e.g. after 3-4 months). |
| Reasons why insulin Toujeo® 300units/mL has been chosen in preference to drugs without Formulary restrictions: | **Nocturnal hypoglycaemia**<br>Patients with Type 1 or Type 2 diabetes who are experiencing nocturnal hypoglycaemia despite being managed intensively on other insulin basal analogues.<br>The hypoglycaemic episodes have been proved by review of data recorded on home blood glucose diary or blood glucose meter or a continuous glucose monitor (CGMS).<br>**AND**<br>**≥80 units of basal analogue insulin**<br>Patients on a high daily dose (defined as 80 units or more) may experience more pain on injection and pooling of insulin, leading to reduced efficacy. The use of Toujeo® 300units/mL insulin will mean that the injection volume is reduced significantly.<br>**Note: patients on high doses of pre-mixed analogues e.g. Novomix 30® are not eligible to be changed to Toujeo® 300units/mL.** |

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| Special precautions: | **Administration:-** Is available as a Toujeo® 300units/mL SoloStar and DoubleStar pre-filled pens. The SoloStar pen dials the dose in steps of 1 unit and the DoubleStar pen dials up in steps of 2units. The dose window shows the number of Toujeo® units to be injected. The Toujeo®300units/mL pre-filled pens have been specifically designed for Toujeo®300units/mL, therefore no dose re-calculation is required.<br><br>**Avoidance of medication errors:-** There are two strengths of insulin glargine available which are 100 units/mL and 300 units/mL.<br><br>Patients must be instructed to;<br>✓ always check the insulin label before each injection to avoid accidental mix-ups between the different strengths of insulin glargine.<br>✓ visually verify the number of selected units on the dose counter of the pen. Patients who are blind or have poor vision should be instructed to get help/assistance from another person who has good vision and is trained in using the insulin device.<br><br>Prescribers/Healthcare staff<br>✓ All prescriptions should specify the brand name of the insulin.<br>✓ All healthcare staff should be aware that insulin should never be withdrawn from an insulin pen using a syringe as severe overdose can result.<br>✓ Clinicians accepting responsibility for Toujeo®300units/mL should ensure that their organisation is aware of the risks associated with prescribing and/or administering high strength vs. standard strength of insulin, and a risk assessment has been completed. Guidance is available on the APC website<br>✓ Ensure patient has the correct insulin passport<br><br>**Hyperglycaemia**:- Inadequate dosing or discontinuation of treatment, especially in type 1 diabetes, may lead to hyperglycaemia and diabetic ketoacidosis.<br><br>**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.<br><br>**Transfer from other insulin medicinal products**:- **Switching should only be done with the advice of the specialist diabetes team**. Toujeo®300 units/mL is a high strength insulin which is not interchangeable with other long acting insulins. Insulin glargine 100 units/mL and Toujeo®300units/mL are not bioequivalent and are not directly interchangeable.<br><br>When switching from insulin glargine 100 units/mL to Toujeo® 300units/mL, this can be done on a unit-to-unit basis, but a higher Toujeo®300units/mL dose (approximately 10-18%) may be needed to achieve target ranges for plasma glucose levels.<br><br>When switching from Toujeo® 300units/mL to insulin glargine 100 units/mL, the dose should be reduced (approximately by 20%) to reduce the risk of hypoglycaemia.<br><br>**Combination of pioglitazone and insulin medicinal products:-**Cases of cardiac failure have been reported when pioglitazone was used in combination with insulin, especially in patients with risk factors for development of cardiac failure. Prescribing of Toujeo 300units/mL and pioglitazone should only be done with diabetes specialist advice. If the combination is used, patients should be observed for signs and symptoms of heart failure, weight gain and oedema. Pioglitazone should be discontinued if any deterioration in cardiac symptoms occurs. |

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| | **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. |
| Pre-treatment test results: **(specialist to complete)** | Date:<br><br>HbA1c (mmol/mol):<br><br>Six month review date : |

**Guidance on initiation**

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| Initiation criteria: **(specialist to complete)** | Specialist:- please tick and complete both boxes<br><br>☐ Nocturnal hypoglycaemia which has been confirmed by home blood glucose monitoring or on a continuous blood glucose monitor **AND**<br><br>☐ Is taking >80units of basal analogue insulin |
| Current Toujeo® 300 units/mL Insulin dose: | **Specialist to complete**<br><br>……UNITS and patient has been stabilised on this dose |
| Insulin passport | ☐ Tick to confirm patient has been given insulin passport |

**Suggested Criteria for Continuation or Discontinuation**

| **Assessment of Efficacy** | |
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| Prescribing Responsibility | Clinicians accepting responsibility for Toujeo®300units/mL should ensure that their organisation is aware of the risks associated with prescribing and/or administering high strength vs. standard strength of insulin, and a risk assessment has been completed. Guidance is available on the APC website. |
| Frequency: | 3 monthly review of HbA1c.<br>Record frequency/severity of nocturnal hypoglycaemic episodes. |
| Location: | Outpatients' clinic/GP practice. |
| Continuation Criteria: | Reduction in frequency of nocturnal hypoglycaemic episodes |
| Discontinuation Criteria: | Where there is no significant reduction in the frequency of nocturnal hypoglycaemic episodes Toujeo® 300units/mL insulin will be stopped. |
| Follow up action: | Review response in 3 months. If no response, consider alternative insulin and refer to specialist. |
| Shared Care Read code: | In the patients 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 |
|---|---|---|
| EMIS and Vision | 8BM5.00 | Shared care prescribing |
| SystmOne | XaB58 | Shared care |