Rationale for Initiation, Continuation and Discontinuation (RICaD)

Insulin degludec 100 units/mL
To avoid the use of an insulin pump in patients with Type 1 diabetes who have nocturnal/severe hypoglycaemia as defined in NICE TA 151 OR recurrent DKA despite good compliance with current insulin regime

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**	
Name		**GP Name**	**Dr**	**Specialist Name**	
PID		**GP address**		**I confirm that this patient is eligible to receive insulin degludec under the restrictions listed below**	
DOB				**Signature**	
Patient address				**Date**	
				Contact details	

Rationale for Choice

Specialist to complete	
Relevant Diagnosis:	This RICaD only supports the prescribing of insulin degludec **100 units/mL** in patients with Type 1 diabetes in line with the indications below.
Agreed Indication(s) for inclusion in the BSSE APC Formulary:	**1. Nocturnal/Severe Hypoglycaemia (with or without hypoglycaemic unawareness) in patients who would otherwise progress to insulin pump treatment as per NICE TA 151.** **OR** **2. Recurrent DKA episodes despite good compliance and who would otherwise progress to insulin pump therapy.**
Reason why insulin degludec has been chosen in preference to drugs without Formulary restrictions:	**1. Nocturnal/Severe Hypoglycaemia** Patients with Type 1 diabetes who are experiencing nocturnal or severe hypoglycaemia (with or without hypoglycaemic unawareness) or being at very high risk for these events, despite being managed intensively on other insulin analogues with support from structured education. (Severe hypoglycaemia here is defined as any hypoglycaemic episode requiring third party assistance such as A+E attendance or requiring paramedic or other healthcare professional assistance). 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). **2. Recurrent DKA despite good compliance** Patients being admitted with recurrent diabetic ketoacidosis (DKA) defined as having 2 or more admissions in a year for DKA and where no compliance issues with insulin injections have been identified.

Special precautions:	**Hyperglycaemia**:- Inadequate dosing or discontinuation of treatment, especially in type 1 diabetes, may lead to hyperglycaemia and diabetic ketoacidosis. **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. In case of hypoglycaemia or if hypoglycaemia is suspected, basal insulin must not be injected. **Transfer from other insulin medicinal products**:- Transferring a patient to another type or brand of insulin should be done under strict medical supervision. Changes in strength, brand (manufacturer), type, origin (animal insulin, human insulin or insulin analogue) and/or method of manufacture (recombinant DNA versus animal source insulin) may result in the need for a change in dose. **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. This should be kept in mind if treatment with the combination of pioglitazone and insulin degludec is considered. 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. **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. **Avoidance of medication errors:-** There are two strengths of insulin degludec available which are 100 units/mL and 200 units/mL. Patients must be instructed to always check the insulin label before each injection to avoid accidental mix-ups between the different strengths of insulin degludec and other insulin products.
Pre-treatment test results: **(specialist to complete)**	Date: HbA1c (mmol/mol): Six month review date :

Guidance on initiation

Initiation criteria: **(specialist to complete)**	Specialist:- please tick and complete the appropriate boxes ☐ **Nocturnal Hypoglycaemia** which has been confirmed by continuous blood glucose monitoring or on home blood glucose meter which otherwise would require patient to start on insulin pump therapy. ☐ **Severe hypoglycaemic episodes which have resulted in 3rd party assistance on more than 2 occasions within 1 year** and otherwise would require patient to start on insulin pump therapy. ☐ **Recurrent DKA (more than 2 admissions within 1 year) despite good compliance and who would otherwise progress to insulin pump therapy.**
Current insulin degludec (100 units/mL) dose:	Specialist to complete ……

Suggested Criteria for Continuation or Discontinuation

<table>
<tr><th colspan="2">Assessment of Efficacy</th></tr>
<tr><td>Frequency:</td><td>3 monthly review of HbA1c.
Record frequency/severity of nocturnal hypoglycaemic episodes .
Record frequency of hospital admissions for DKA despite good compliance with insulin injections.</td></tr>
<tr><td>Location:</td><td>Outpatients' clinic/GP practice.</td></tr>
<tr><td>Continuation Criteria:</td><td>Reduction in frequency of nocturnal or severe hypoglycaemic episodes.
OR
Reduction in frequency of hospital admissions for DKA.</td></tr>
<tr><td>Discontinuation Criteria:</td><td>Where there is no significant reduction in the frequency of nocturnal and/ or severe hypoglycaemia episodes after 6 months of treatment, insulin degludec will be stopped.
OR
Where there is no significant reduction in frequency of hospital admissions after 6 months of treatment, insulin degludec will be stopped.</td></tr>
<tr><td>Follow up action:</td><td>Review response in 6 months. If no response, consider alternative insulin and refer to specialist.</td></tr>
<tr><td>Shared Care Read code:</td><td>In the patients notes, using the appropriate Read code listed below, denote that the patient is receiving treatment under a shared care agreement.
<table><tr><th>GP Prescribing System</th><th>Read Code</th><th>Description</th></tr><tr><td>EMIS and Vision</td><td>8BM5.00</td><td>Shared care prescribing</td></tr><tr><td>SystmOne</td><td>XaB58</td><td>Shared care</td></tr></table></td></tr>
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