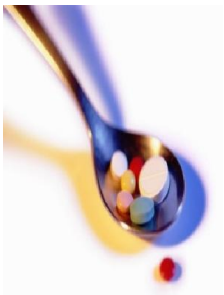

NewTherapiesSubgroup

GMMMG Greater Manchester Medicines Management Group

NHS

20th May 2015

Insulin Degludec & Liraglutide (Xultophy®▼) for the treatment of adults with type 2 diabetes inadequately controlled on a basal insulin analogue.

The New Therapies Subgroup (NTS) discussed the above drug at a meeting in May 2015. The recommendation of this subgroup is as follows:*

The New Therapies Subgroup of the GMMMG considered the use of Insulin Degludec & Liraglutide (Xultophy®▼) for the management of adults with type 2 diabetes.

The group does not recommend the use of the combination product Xultophy® for the above indication.

The fixed-dose ratio of the combination product does not allow for the insulin and GLP-1 analogue doses to be titrated separately in order to optimise individual patient diabetes control. For patients receiving doses of insulin degludec of 34 units and up to 50 units the group noted that they will receive between 1.2 and 1.8mg of liraglutide. The use of liraglutide in doses above 1.2mg is not recommended as results from a meta-analysis showed no significant difference between liraglutide 1.2mg and liraglutide 1.8mg in terms of patients reaching an HbA1c level of less than 7%.

As per NICE guidance Neutral Protamine Hagedorn (NPH) insulin is the preferred treatment option for type 2 patients who require insulin.

The use of long acting insulin analogues in type 2 diabetes should only be considered if deemed clinically appropriate. i.e. failure to maintain glycaemic control overnight and in whom nocturnal hypoglycaemia is an issue despite optimisation of medication regimen or those with an unpredictable lifestyle e.g. shift workers. If classed as appropriate the preferred long acting insulin analogue is insulin glargine as outlined within the GMMMG formulary. Insulin degludec is not routinely recommended.

Other than administration of a single daily injection, additional clinical benefit over using separate basal insulin and GLP-1 analogue agents concomitantly has not been demonstrated.

According to set criteria Xultophy® was deemed to be a low priority for funding

Review date: May 2017

* Unless superseded by NICE guidance or substantial and significant new evidence becomes available.
▼ Newly marketed drugs and vaccines are intensively monitored for a minimum of two years, in order to confirm the risk / benefit profile of the product. Healthcare professionals are encouraged to report all suspected adverse drug reactions regardless of the severity of the reaction.

Commissioning implications for CCGs

NTS Recommendation

The recommendation deems this drug a low priority for funding. Insulin degludec has been re-reviewed and also remains a low priority for funding [see updated recommendation].

Xultophy® is a fixed dose of insulin degludec 100units and liraglutide 3.6mg per ml. The dose is usually stated in terms of the insulin dose and that is expected to indicate a maximum dose of 50 units. A 50 unit dose will provide 1.8mg of liraglutide which is not recommended by NICE in Technology Appraisal 203 [http://www.nice.org.uk/guidance/TA203]. NICE recommends a dose of 1.2mg liraglutide which would be equivalent to approximately 33 units. However, this Technology Appraisal will be superseded by the updated clinical guideline for Type 2 diabetes due in October 2015. The draft of this updated guideline makes no reference to an insulin / GLP-1 combination as none were licensed before NICE's cut-off date for consideration of evidence / products.

Diabetes is a very high cost area both nationally and in all GM CCGs.
There is almost a 2-fold difference in costs per patient between GMCCGs for this marker.

Future commissioning implications

There are not expected to be any significant future financial or commissioning implications.

Formulary and Interface considerations

The drug is not in the Greater Manchester Formulary, nor on the Do Not Prescribe list. As a low priority for funding, it would be anticipated that this would not enter the formulary. Patients are usually initiated on GLP-1 analogues after the involvement of a Secondary Care Consultant or Tier2 diabetes service. There could be additional financial implications associated with attendance at these services should there be significant interest in this preparation and if the recommendation is not followed.

The Interface group may reconsider RAG status although insulins and GLP-1s used together have already been recommended as green after specialist initiation which is in line with the recommendation in NICE's draft Type 2 diabetes update that GLP-1s in combination with insulin should only be offered in a specialist care setting.

Summary of impact

Impact is expected to be minimal. The product has been priced at £159.22 for five 3ml pens which is the same price as using liraglutide with **one of the other** basal insulin analogues [detemir or glargine] separately but slightly cheaper than liraglutide in conjunction with degludec.

Major area of risk / implications: primary care