AREA PRESCRIBING COMMITTEE MEETING
Birmingham, Sandwell, Solihull and environs

Minutes of the meeting held on
Thursday 14th January 2021
Venue – Microsoft Teams

PRESENT:

Dr Paul Dudley	Birmingham and Solihull CCG (Chair)
Dr Lisa Brownell	BSMHFT
Nigel Barnes	BSMHFT
Prof Mark Dasgupta	Birmingham and Solihull CCG
Nilima Rahman-Lais	Birmingham and Solihull CCG
Dr Nashat Qamar	Birmingham and Solihull CCG
Liz Thomas	Birmingham and Solihull CCG
Dr Sonul Bathla	Sandwell and West Birmingham CCG
Satnaam Singh Nandra	Sandwell and West Birmingham CCG
Emily Horwill	Sandwell and West Birmingham NHST
Dr Sangeeta Ambegaokar	Birmingham Women's and Children's NHS FT
Melanie Dowden	Birmingham Community Healthcare NHS FT
Carol Evans	UHB NHS FT/ Birmingham and Solihull CCG
Gurjit Sohal	UHB NHS FT
Dr Jeff Aston	UHB NHS FT
Jonathan Horgan	Midlands and Lancashire CSU
Graham Reader	Midlands and Lancashire CSU
Daya Singh	Midlands and Lancashire CSU

IN ATTENDANCE:

Prof Wasim Hanif for item 0121/05	UHB NHS FT
Dr Karen Tait for item 0121/05	Birmingham Community Healthcare NHS FT
Amna Esposito for item 0121/05	Birmingham and Solihull CCG
Sharon Coane for item 0121/05	Birmingham and Solihull CCG
Hanadi Alkhder for item 0121/05	Birmingham and Solihull CCG

No.	Item	Action

0121/01 Apologies for absence were received from:

Dr John Wilkinson, Birmingham and Solihull CCG
Dr Dhiraj Tripathi, UHB NHS FT
Prof Jamie Coleman, UHB NHS FT
Dr Mark Pucci, UHB NHS FT
Jonathan Boyd, Sandwell and West Birmingham CCG
Alison Tennant, Birmingham Women's and Children's NHS FT

It was confirmed that the meeting was quorate.

0121/02 Items of business not on agenda

No other items of business were discussed

0121/03 Declaration of Interest (DoI)

The Chair reminded members to submit their annual declarations of interest to the APC secretariat.

0121/04 Welcome and Introductions

The Chair reminded members, that the meeting is digitally recorded for the purpose of accurate minute taking and once the minutes are approved, the recording is deleted by the APC secretary.

0121/05 DMMAG documents

Diabetes Medicines Management Group (DMMAG) members attended the meeting for this item.

The Treatment & Management of Hypoglycaemia in Adults with Diabetes Mellitus was presented to the committee. The guideline consolidates several resources into one document. It was noted that the guideline includes recommendations on the prescribing of GlucoGel® and Rapilose® gel.

It was explained, that due to Covid-19, insulin therapy is being initiated in primary care with very little or no support from secondary care. The Insulin Prescribing Pathway aims to support primary care clinicians to do so.

A new drug application for Insulin aspart (Fiasp®) was introduced to the committee. Dr Tait explained that Fiasp® is currently on the formulary for use in pregnant women with either gestational diabetes or pre-existing diabetes and requested expansion for its use in all people with Type 1 diabetes according to the criteria:
1. Patients with T1DM on MDI to improve postprandial control if HbA1c >69mmol/mol despite adequate fasting and pre-meal glucose. May avoid high cost treatment such as insulin pump therapy.
2. Patients with T1DM on CSII to improve postprandial control if HbA1c >69 mmol/mol is elevated despite adequate fasting and pre-meal BG. May avoid need for higher cost treatment such as Freestyle Libre or CGMS.
3. Preconception to achieve tight postprandial control.
4. When it is difficult to consistently optimally time mealtime insulin bolus 10-15 minutes pre meals for example work or family circumstances, eating out.

It was explained that the main difference between Fiasp® and NovoRapid® is the time of onset, peak action, and duration of action. Fiasp® can be administered two minutes before meals and up to twenty minutes from starting the meal whereas NovoRapid® and other available mealtime insulins need to be given ten-fifteen minutes before meals. It was noted that the Onset clinical trial programme demonstrated some reduction in HbA1c both in adults and children and achieved a better control of post meal blood glucose. Dr Tait explained that NovoRapid®, Humalog® and Apidra® would remain as first line mealtime insulins and is proposing Fiasp® to be used second line as specialist recommendation in a defined group of patients. Dr Tait stated that a third of patients struggle to take their mealtime insulins at the correct time, therefore it would be convenient for patients to be able to administer Fiasp® nearer to mealtime. Dr Tait also requested to extend the use in preconception, to achieve tight postprandial control and would like to retain Fiasp® use for existing indications.

Discussion points raised included:

- It was suggested that the Hypoglycaemia guideline should include contact details for who clinicians can contact if they have any queries.
- Members agreed the Hypoglycaemia guideline and Insulin Prescribing Pathway were excellent and extended their thanks onto the DMMAG.
- It was asked whether DMMAG can consider producing a similar document to the hypoglycaemia management guideline for patients that are at risk of hypoglycaemia.
- It was raised that the criteria for Fiasp® mentions post prandial control however, clarification was sought on what this means in practice in terms of better patient outcomes. Dr Tait explained that post prandial hyperglycaemia contributes significantly to higher HbA1c, as patients can have well controlled fasting and pre-meal blood glucose readings but are still out of target and this is due to post prandial hyperglycaemia.
- It was raised that the application does not demonstrate an impact on HbA1c which is of clinical significance and the trial conclusions on HbA1c seem to suggest non inferiority and not superiority. In the registration trials there was a small HbA1c reduction, which could have been due to larger doses of Fiasp® being administered in the trial versus the aspart group. Dr Tait responded that in terms of patient factors, patients do not take their mealtime insulin as recommended or do not take it all because they have either forgotten and cannot take it after a meal or they do not know when they will eat. It was raised that Fiasp® will prevent this barrier for patients that don't take mealtime insulins as they should be, for example, patients who are working.
- It was raised that whilst HbA1c has been accepted as a marker of whether patients are meeting a pre-defined target in Type 2 diabetes, Time-In-Range (TIR) is becoming a more widely used marker in Type 1 diabetic patients and secondary care colleagues are embracing this change.
- It was noted that the trials did not look at Time-in-Range.
- There was discussion on the upcoming availability of a biosimilar version of aspart (NovoRapid®). It is expected that this will be launched imminently.
- It was asked how many patients as a percentage from the Type 1 diabetes cohort would be switched onto Fiasp®. It is estimated 10-20% of Type 1 diabetics patients would switch and this would be by specialist recommendation.

- It was asked whether the APC would consider including preconception as an indication for the use of Fiasp® even if other cohorts were not approved, as this would be desirable for maternity teams who are currently unable to initiate patients who are planning on becoming pregnant on Fiasp®.

The Chair thanked DMMAG representatives for attending the meeting, and advised them that the decision would be relayed within 5 working days, in line with APC policy.

Further discussion points then included:

- It was noted that whilst there are post prandial targets set in NICE guidance for pregnancy, there are none set for the preconception stage. It was also raised that there is no way of determining how long a woman would fit into the preconception category.
- It was raised that there is a clear differentiation in the registration trials in that more insulin was used in the Fiasp® group compared to the aspart group. In addition, Time-In-Range was not measured for Fiasp® in the trials.
- It was noted that the insulin prescribing pathway described above includes the proposed use of Fiasp®, but if that is not approved it should be amended to refer only to for existing approved position in pregnant patients.

The committee completed the Decision Support Tool for **Fiasp®** as follows:

Patient Safety: No difference compared to existing agents

Clinical effectiveness: Clear evidence non-inferiority to comparator. Lack of evidence to support superiority for HbA1c.

Strength of evidence: Evidence for difference in post prandial glucose profile in Randomised Controlled Trials (RCT)

Patient factors: Evidence of moderate improvement in flexibility of dosing relative to meals particularly in paediatric cohort.

Cost effectiveness or resource impact: Currently cost-neutral for existing NovoRapid® patients. Biosimilar version of aspart (NovoRapid®) will shortly become available, at likely lower cost

Place of therapy relevant to available treatments: 2nd line, within Type 1 diabetic cohort

National guidance and priorities: n/a

Local health priorities: Lack of evidence to extend use further in the type 1 diabetes population

Equity of access: n/a

Stakeholder views: n/a

Implementation requirements: RICaD would be required if extension of use were to be accepted

Prescribing data: Yes, if approved

Decision Summary: Not approved

Rationale: No evidence regarding improvement time in range measurement, or for compelling reduction in HbA1c when compared to Insulin aspart. Insufficient evidence to extend cohort. No national targets in pre-conception cohort.

Formulary status (RAG) and rationale: Unchanged for gestational diabetes

Implementation requirements: DMMAG to amend insulin prescribing pathway please, to reflect the current formulary status, not the proposed status

Implementation monitoring e.g. prescribing data: n/a

The Committee approved the Hypoglycaemia guideline and Insulin Prescribing Pathway subject to the amendments being carried out as specified in Actions below.

ACTIONS:

- **DMMAG to amend the guideline for hypoglycaemia with inclusion of contact details who clinicians can contact if they have any queries, approved for publication once amended.** **DMMAG / APC Sec**
- **DMMAG to amend the Insulin prescribing pathway to remove the proposed additional categories of patients for whom Fiasp may be prescribed and replace with that currently approved in the formulary, approved for publication once amended.**
- **Relay decision to DMMAG by Thursday 21st January 2021**

0121/06 BSSE APC RICaD for review – for ratification

The Chair presented the Entresto® RICaD.

No comments were received. This was approved.

ACTIONS:

- **Publish Entresto® RICaD on APC website** **APC Sec**

0121/07 ESCA wording for historic patients – for discussion

It was agreed during the December 2020 APC meeting to add additional wording to reflect the APC's position on the use of ESCAs to the APC Policy and ESCA document template.

Discussion points raised included:

- It was agreed to add 'retrospectively' in front of 'for patients who have already been prescribed a medication" and add 'in primary care' after it, to the proposed wording.
- It was agreed for the wording to be added to page 2 of the ESCA template within the top paragraph.
- It was agreed to annotate the ESCA section of the APC website with the proposed wording.

ACTIONS:

- **Amend APC policy in line with above comments and publish.**
- **Amend ESCA template in line with above comments.** **APC sec**
- **Annotate ESCA section of APC website with approved wording.**

0121/08 Declines by Trust DTC
None were reported

0121/09 RMOC recommendations
There were no RMOC recommendations to report on in December 2020.

0121/10 Minutes of the meeting held on Thursday 10th December 2020 – for ratification.

The minutes of the meeting held on Thursday 10th December 2020 were discussed for accuracy.

- Page 7: Expand details of discussions on Low Molecular Weight Heparin (LMWH) discussion at the meeting
- Page 8: Remove bullet point '0719/06: BSSE APC away documents: Close action'

It was confirmed that subject to a virtual approval of the revised minutes to be circulated to members, the minutes are approved and can be uploaded to the APC website and the recording deleted.

0121/11 Matters Arising
The action table was reviewed for comments and updates:
(See separate document attachment for an updated version). Consider actions closed if not discussed.

The outstanding actions include:

- 1220/05 - Liothyronine - new drug application - Amend ESCA in line with comments mentioned in meeting. In progress
- 1220/13 - Low Molecular Weight Heparin (LMWH) - Circulate LMWH ESCA for consultation. In progress
- 1120/07 - Hydroxycarbamide ESCA for myeloproliferative disorders – for discussion - APC secretary to establish generic license for hydroxycarbamide Medac ESCA. Trust to liaise with specialist to confirm ESCA. In progress.
- 1120/08 - Phenobarbitone liquid – for discussion. BWC NHSFT to bring formal wording for phenobarbitone formulary entry. February 2021
- 1120/06 - Buprenorphine oral lyophilisate (Espranor®) – new drug application - CCG to write to commissioner at city council to clarify rationale for CGL use of Espranor®. In progress.
- 1020/05 – Colesevelam (Cholestagel®) and Colestipol (Colestid®) new drug application – Amend RiCaDs in line with comments mentioned in meeting. In progress.

- 1020/08 – Trust DtPs and DTC non-formulary approvals – Circulate UHB NHSFT template for Decline to Prescribe non-formulary approvals. In progress.

- 0619/AOB - Azathioprine for haemolytic anaemia - Produce Azathioprine ESCA for haemolytic anaemia. In progress.

0121/12 NICE Technological Appraisals (TAs)

In December 2020, there were 5 TAs published; 3 are NHSE commissioned and 2 are CCG commissioned.

The CCG commissioned NICE TAs are:

- Upadacitinib for treating severe rheumatoid arthritis [TA665]
- Liraglutide for managing overweight and obesity [TA664]

Red status agreed for both.
ACTION: Update formulary with NICE TAs.

Any other business:

None was discussed

The meeting closed at 15:45.
Date of next meeting: Thursday 11th February 2021 via Microsoft Teams