NHS GRAMPIAN
Minute of Formulary Group Meeting
Tuesday 18 July 2017 at 14:30 in the Board Room, Aberdeen Royal Infirmary

PRESENT	APOLOGIES	APPROVED
Ms A Davie	Dr D Culligan	
Ms F Doney	Dr L Elliot	
Mrs L Harper	Dr J Fitton	
Dr C Hind	Mrs J Jordan	
Dr A MacDonald		
Professor J McLay (Chairman)		
Mrs L Montgomery		
Dr W Moore		
Mr M Paterson		
Mr C Rore		
Mr R Sivewright		
Dr A Sun		

IN ATTENDANCE
Dawn Bruce, Specialist Pharmacy Technician Formulary Team

ITEM	SUBJECT	ACTION
	The Chairman opened the meeting, welcomed everyone, and noted that a quorum was present.	
1.	**APOLOGIES**	
	Apologies for absence were requested and noted.	
2.	**DRAFT MINUTE OF THE MEETING HELD 20 JUNE 2017**	
	The draft minute was issued the day before the meeting so members were given a week to return any comments to Ms Doney. The Group ratified the minute subject to any changes required due to comments received.	**All** **FD**
3.	**PRESENTATION**	
	Dr Sun discussed the potential use of insulin degludec in a defined group of paediatric patients. She confirmed that insulin degludec was not painful to administer, and the paediatric service had used insulin degludec for a small group of paediatric patients with positive results (reduction in ketotic episodes/admission for diabetic ketoacidosis (DKA)).	
4.	**MATTERS ARISING**	

4.1. SMC 1060/15 - INSULIN DEGLUDEC (TRESIBA®) ▼ (DIABETES MELLITUS IN ADOLESCENTS AND CHILDREN FROM 1 YEAR OLD)

There were no declarations of interest recorded in relation to this product.

The Group considered the request to make insulin degludec available in NHS Grampian for a restricted group of paediatric patients.

The Group noted that:
- degludec:
  - was accepted to formulary for adults in line with SMC advice (SMC 856/13)
  - is licensed for adolescents and children from the age of 1 year, but it was not accepted for use in NHS Scotland because the holder of the marketing authorisation has not made a submission to SMC
  - is an ultra-long acting basal insulin given once-daily by subcutaneous injection, has a long duration of action (at least 42 hours)
  - is available as 100units/mL and 200units/mL preparations but the use of high strength insulin is not supported locally so the request is limited to the 100units/mL preparation
- there is no clinical experience with flexibility in dosing time [of insulin degludec] in children and adolescents
- in type 1 diabetes mellitus, insulin degludec must be combined with short-/rapid-acting insulin to cover mealtime insulin requirements

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- some teenager patients do not comply with the other available long acting insulins (insulin detemir - requires twice daily dosing; insulin glargine – painful to administer so patients do not take full dose or refuse to take it)

The Group noted that the long duration of action may provide a particular advantage for some teenagers with poor compliance with other long-acting insulins, and that are regularly admitted with DKA or those at a higher risk of DKA.

The Group accepted the restricted local need for insulin degludec 100units/mL for the treatment of diabetes mellitus in paediatric patients, prescribing should be limited to consultants/only prescribed on the advice of a consultant diabetologist.

SMC 1060/15 - Insulin degludec 100units/mL solution for injection in pre-filled pen or cartridge (Tresiba®) ▼ is routinely available in line with local guidance.
Indication under review: the treatment of diabetes mellitus in adolescents and children from the age of 1 year. It was classified 1b- available for restricted use under specialist supervision and 8d - treatment may be initiated in the community on the recommendation of a consultant/specialist. Prescribing should be limited to consultants/only prescribed on the advice of a consultant diabetologist. **FTeam**

4.2. APREPITANT IN PAEDIATRICS

It was confirmed that submissions for the use of aprepitant in paediatrics are expected and will be considered at a future meeting.

4.3. NEOMAG® 4MMOL CHEWABLE TABLETS

Abbreviated SMC advice for the newly licensed magnesium preparation, Neomag® chewable tablet, is planned for publication September 2017. If accepted for use in NHS Scotland Mr Rore will lead the submission, provide the Group with a comparison to current formulary options, and if required update the current hypomagnesaemia policy. **CR**

5. FORMULARY GROUP DECISIONS JUNE 2017 - PUBLISHED 04/07/2017

The Group noted the published June decisions.

6. NETFORMULARY/FORMULARY REVIEW

6.1. INTRAVAGINAL OESTROGENS

There were no declarations of interest recorded in relation to these products.

Review of the current formulary choice intravaginal oestrogens highlighted that Estring® is currently non-formulary, and a change in price of estriol 0.01% w/w cream.

Estring® is a vaginal ring that releases estradiol at an average of 7.5microgram/24 hours, over 90 days. It is prescribed locally, and costs significantly more that Ovestin® but is comparable with Vagifem® pessaries. The local specialist supports formulary inclusion, as it would be useful for older patients and for patients who cannot use cream or pessaries.

The Group supported formulary inclusion of Estring® without the need for full submission.

Estradiol 7.5microgram/24 hours vaginal delivery system (Estring®) is routinely available in line with local guidance.
Indication under review: treatment for atrophic vaginitis, (due to oestrogen deficiency) in postmenopausal women. It was classified 1b - available for restricted use under specialist supervision and 8d - treatment may be initiated in community on the recommendation of a consultant/specialist. The maximum recommended duration of continuous therapy is two years. **FTeam**

Gynest® cream with applicator was discontinued by Marlborough Pharmaceuticals late 2014, a generic version of the product was available at that time. Marlborough remains the main Marketing Authorisation Holder for the 0.01% cream. Although Gynest® is listed in both eMC and BNF the product is not available. The generic product, now renamed Estriol 0.01% w/w cream, costs significantly more that Gynest® (£24.98 vs. £4.67).
Ovestin® 1mg cream is an alternative intravaginal oestrogen. It provides the same

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therapeutic dose of estriol (0.5mg) in a much smaller volume of cream (0.5g versus 5g) so is more cosmetically acceptable for patients.

The Group recommended removing estriol 0.01% intravaginal cream from the formulary. A member requested an IMPACT article regarding the change. **FTeam**

Estriol 0.01% cream with applicator is not routinely available as there is a local preference for an alternative medicine.
Indication under review:
- hormone replacement therapy for treatment of atrophic vaginitis and kraurosis in postmenopausal women
- treatment of pruritus vulvae and dyspareunia associated with atrophic vaginal epithelium
Not routinely available as there is a local preference for an alternative medicine. **FTeam**

6.2. MENTAL HEALTH SECTIONS

Ms Doney confirmed that the mental health sections of the formulary are currently under review.

The Group reviewed the chart showing the comparative cost of antidepressant drugs. The high cost of trazodone and venlafaxine were noted. The cost of trazodone 50mg/5mL oral solution was not included on the chart, as its cost would have skewed the data (150mg daily would cost over £7,000 per annum (SDT July 2017)).

The Group discussed the use of trazodone solid dosage forms and considered that use as a single agent represents established patients/historical use. It was confirmed that some Consultant Psychiatrists use trazodone as an adjunct/find it a useful drug alongside SSRIs where there is persistent sleep disturbance. Removal from formulary is not an option at this time. The use of trazodone liquid could be reviewed at individual patient level to ensure that a liquid formulation is required.

7. OTHER BUSINESS

7.1.1. NICE MTA 449 EVEROLIMUS AND SUNITINIB FOR TREATING UNRESECTABLE OR METASTATIC NEUROENDOCRINE TUMOURS IN PEOPLE WITH PROGRESSIVE DISEASE

There were no declarations of interest recorded in relation to these products.

METASTATIC NEUROENDOCRINE TUMOURS OF PANCREATIC ORIGIN
Everolimus (SMC 777/12) and sunitinib (SMC 698/11) were accepted to formulary as options for treating well- or moderately-differentiated unresectable or metastatic neuroendocrine tumours (NETs) of pancreatic origin in adults with progressive disease. The NICE and SMC recommendations are consistent. As the NICE MTA guidance supersedes SMC advice, the Group ratified the recommendations of TA449 in relation to this indication. For sunitinib the advice remains contingent upon the continuing availability of the Patient Access Scheme in NHS Scotland. **FTeam**

METASTATIC NEUROENDOCRINE TUMOURS OF GASTROINTESTINAL OR LUNG ORIGIN
Everolimus for neuroendocrine tumours of gastrointestinal or lung origin, (SMC 1215/17) is currently recorded as “Not routinely available as the ADTC is waiting for further advice from local clinical experts.” The Formulary Team will contact the service and confirm if a local need exists for everolimus as per TA449. **FTeam**

7.1.2. NICE MTA 455 ADALIMUMAB, ETANERCEPT AND USTEKINUMAB FOR TREATING PLAQUE PSORIASIS IN CHILDREN AND YOUNG PEOPLE

There were no declarations of interest recorded in relation to these products.

It was confirmed that the NICE advice was published after the meeting papers were issued and this paper replaces item 8.2 on the agenda.

The Group noted that:
- the SMC has previously issued guidance to NHS Scotland on the use of etanercept,

adalimumab and ustekinumab in this indication
- when considering the status of etanercept included in SMC or NICE advice, etanercept includes biosimilar agents licensed for the treatment of psoriasis in children and adolescents, it is not restricted to the reference product Enbrel®
- overall, the recommendations are consistent. The main differences are:
  - the definition of severe disease for etanercept and adalimumab.
    SMC defined severe disease as - a total Psoriasis Area Severity Index (PASI) score of 10 or more and a Dermatology Life Quality Index[1] (DLQI) of >10. [NICE defines severe psoriasis as PASI of 10 or more, no link with DLQI score].
  - ustekinumab was accepted by SMC for moderate to severe psoriasis, NICE restricts use to patients with severe psoriasis (i.e. PASI ≥10).
- stopping rules are consistent between SMC and NICE. If psoriasis has not responded adequately, stop etanercept at 12 weeks, stop adalimumab and ustekinumab at 16 weeks. Stopping rules are consistent with licensing apart from ustekinumab, the SmPC states response should be assessed at 28 weeks, rather than 16 weeks.
- the British Association of Dermatologists guidelines strongly recommend that all psoriasis patients on biologic therapies should be registered with The British Association of Dermatologists' Biologic Interventions Register (BADBIR)
- Dermatology Consultants confirm that local use of biologic agents for the treatment of psoriasis in children and adolescents is in line with the NICE advice
- Healthcare Improvement Scotland (HIS) is due to issue advice to NHS Scotland regarding TA455 week commencing 25/07/2017

The Group considered that there were no significant or controversial differences between the SMC and NICE recommendations. The Group ratified the recommendations of TA455, subject to HIS issuing positive advice to NHS Scotland. **FTeam**

Ms Doney confirmed that to avoid pre-empting the HIS response and circumventing process, if HIS has not issued advice before the publication timeline for the July Formulary Decisions local advice will be held back until the August meeting.

7.2. SBAR BENEPALI® ▼ 25MG (NEW STRENGTH BIOSIMILAR ETANERCEPT)

The Group considered the SBAR for a new 25mg strength of the biosimilar medicine, Benepali® ▼.

In March 2015, the Group agreed that, as the efficacy and safety of biosimilar medicines is established through the medicines' regulatory processes, biosimilar medicines should be available for prescribing within NHS Grampian without the need for individual formulary submissions - if the original reference product is already on formulary. This position is subject to compliance with the relevant monitoring and governance requirements of a biosimilar medicines prescribing framework.

The Group noted that:
- biosimilar products are considered outwith remit for SMC
- etanercept, as the reference product Enbrel®, is already included on the formulary for the indications noted in the Benepali® ▼ 25mg Summary of Product Characteristics
- Benepali® ▼ 50mg is part of national contract negotiations, including homecare arrangements, and is considered the preferred biosimilar preparation for NHS Scotland
- clarification is required that the 25mg strength will be included in the national contract
- if included in national contract arrangements local use will follow current national/local guidance, e.g. SMC, NICE MTA, recommendations of the Scottish Paediatric and Adolescent Network (SPARN)
- biologic medicines, including biosimilar medicines, should be prescribed by both generic and trade name, and the trade name and batch number should be recorded on the patient's prescription, case record or other appropriate clinical system

[1] DLQI is a questionnaire designed to measure how much a patient's skin problem has affected their life in the last week. http://sites.cardiff.ac.uk/dermatology/quality-of-life/dermatology-quality-of-life-index-dlqi/.

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	Ms Doney confirmed that Enbrel® 10mg vial (for paediatric use) and 25mg vial will remain available for indications/patient groups not included in the Benepali® ▼ 25mg licence.	
	The Group accepted the restricted local need for Benepali® ▼ 25mg without the need for a full submission. Use is subject to clarification that Benepali® ▼ 25mg is a preferred biosimilar preparation for NHS Scotland.	**BW**
	Benepali® ▼ 25mg solution for injection in pre-filled syringe is routinely available in line with national guidance. **Indication: in line with the current SMC and Healthcare Improvement Scotland advice for the reference product etanercept [Enbrel®].** **It was classified 1b - available for restricted use under specialist supervision and 8b - recommended for hospital use only. Treatment should be initiated and supervised by specialist physicians experienced in the diagnosis and treatment of rheumatoid arthritis, juvenile idiopathic arthritis, psoriatic arthritis, ankylosing spondylitis, non-radiographic axial spondyloarthritis, plaque psoriasis or paediatric plaque psoriasis.** **Patients treated with Benepali® ▼ should be given the Patient Alert Card.**	**FTeam**

7.3. GUIDANCE FOR COST-SENSITIVE HIV THERAPY PRESCRIBING IN NHS SCOTLAND 2017

The Group noted the prescribing guidance issued by the Scottish Health Protection Network.

7.4. EPISTATUS® 10MG OROMUCOSAL SOLUTION

Ms Doney reported that Epistatus®, as the multidose unlicensed preparation, was the preferred preparation in NHS Grampian. A new single-use product, Epistatus® 10mg Oromucosal Solution, has been licensed for children and adolescents aged 10 to less than 18 years. This represents a significant change to the current unlicensed product.

The new product is expected to be reviewed by SMC, but any change in preferred choice would have significant training and documentation issues for NHS Grampian and third sector organisations (care plans currently include unlicensed Epistatus®).

8. NEW PRODUCT REQUESTS

8.1. FG1 SMC 1223/17 – IXEKIZUMAB (TALTZ®) ▼ (PLAQUE PSORIASIS - ADULTS)

There were no declarations of interest recorded in relation to this product.

The Group considered the submission for ixekizumab for the treatment of moderate to severe plaque psoriasis in adults who are candidates for systemic therapy. The SMC advice restricts use to patients who have failed to respond to standard systemic therapies (including ciclosporin, methotrexate and phototherapy), are intolerant to, or have a contra-indication to these treatments.

The Group noted:

- ixekizumab:
  - is an IgG4 monoclonal antibody designed to selectively bind to and inhibit interleukin 17A (both IL-17A and IL-17A/F), a pro-inflammatory cytokine
  - is the third interleukin-inhibitor licensed for the treatment of psoriasis (after ustekinumab and secukinumab). The most appropriate comparator is secukinumab (also an IL-17A inhibitor) but there is no direct comparison data for ixekizumab and secukinumab.
- will provide another biologic option for adult patients with moderate to severe psoriasis
- the British Association of Dermatologists guidelines strongly recommend that all psoriasis patients on biologic therapies should be registered with The British Association of Dermatologists' Biologic Interventions Register (BADBIR)
- because of the lack of long-term safety data the service planned to use ixekizumab for patients in whom tumour necrosis factor antagonists and interleukin (IL-12 and IL-23) therapies had failed or are contraindicated
- other biologic medicines used locally are available via homecare suppliers, but the Lilly Homecare offer for ixekizumab was not recommended for use. If used locally costs will include VAT.

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The Group noted the potential increase in costs incurred due to VAT and accepted the restricted local need for ixekizumab as outlined in SMC 1223/17 subject to provision of a suitable homecare arrangement.

SMC 1223/17 - Ixekizumab 80mg solution for injection (Taltz®) ▼ is routinely available in line with national guidance (SMC 1223/17).
Indication under review: moderate to severe plaque psoriasis in adults who are candidates for systemic therapy.
Restriction: patients who have failed to respond to standard systemic therapies (including ciclosporin, methotrexate and phototherapy), are intolerant to, or have a contra-indication to these treatments.
Ixekizumab was superior to placebo and to a tumour necrosis factor (TNF) antagonist for improving symptoms of adults with moderate to severe plaque psoriasis.
This advice takes account of the benefits of a Patient Access Scheme (PAS) that improves the cost-effectiveness of ixekizumab and is contingent upon the continuing availability of the PAS in NHS Scotland or a list price that is equivalent or lower. It was classified 1b - available for restricted use under specialist supervision and 8b - recommended for hospital use only. Ixekizumab is intended for use under the guidance and supervision of a physician experienced in the diagnosis and treatment of psoriasis. **FTeam**

8.2. SBAR – ADALIMUMAB (HUMIRA®) (PAEDIATRIC PSORIASIS)

This item was covered under item 7.1.2.
SMC 1068/15 is superseded by NICE Multiple Technology Appraisal Guidance TA455.

8.3. FG1 399/16 – SILDENAFIL [OFF-LABEL USE] (SEVERE REFRACTORY RAYNAUD'S PHENOMENON)

There were no declarations of interest recorded in relation to this product.

The Group reviewed the submission and first draft of the review of a request for the off-label use of sildenafil. The hope is that the requestor will attend a future meeting. The draft paperwork was sent early to allow members to agree questions that should be considered by the requestor.

The Group noted that:
- Sildenafil:
  - is a phosphodiesterase type 5 (PDE5) inhibitor, licensed for pulmonary arterial hypertension (initiated under specialist supervision, and supplied by the specialist centre) and erectile dysfunction
  - is only prescribable in Primary Care under certain circumstances, only available for the treatment of erectile dysfunction in men who meet the criteria listed in Part 12 of the Scottish Drug Tariff. The prescription must be endorsed 'SLS'.
- the indication was unclear. Is the request for the management of symptomatic Raynaud's, to heal digital ulcers or reduce the number of new ulcers, for progressive systemic sclerosis?
- the anticipated numbers requiring treatment was surprisingly high
- evidence for efficacy was lacking. There are more recent studies (January 2017), the evidence submitted was limited, and did not show evidence for healing digital ulcers.
- the British Society for Rheumatology guidance is in line with NHS England's commissioning policy and does not reflect systems in NHS Scotland

The Group discussed the information submitted at length, and requested that the submission is reviewed to clarify:
- the indication being requested, cohort of patients considered for treatment
- include evidence relevant for the anticipated patient cohort
- treatment pathway for this cohort, and at what point sildenafil will be used in the pathway
- anticipated length of treatment, any monitoring requirements. If long-term use anticipated, potential adverse effects and management **FTeam**

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9. SCOTTISH MEDICINES CONSORTIUM PROVISIONAL ADVICE - ISSUED JULY 2017

The Group noted the SMC provisional advice issued July 2017.

If published next month the negative SMC recommendation, for 5-aminolaevulinic acid (as hydrochloride) (Ameluz®) SMC 1260/17, and the non-submission statements, for canakinumab (Ilaris®) SMC 1268/17, follitropin delta (Rekovelle®) ▼ SMC 1269/17 and sufentanil citrate (Zalviso®) SMC 1270/17, will not be included on the Grampian Joint Formulary for the indications in question. **FTeam**

10. SCOTTISH MEDICINES CONSORTIUM PRESS STATEMENTS - PUBLISHED JULY 2017

The Group noted the SMC advice published July 2017.

Following publication of the negative SMC recommendation, for selexipag (Uptravi®) ▼ SMC 1235/17, and the non-submission statements, for emtricitabine/tenofovir disoproxil (Truvada®) SMC 1263/17 and trametinib (Mekinist®) ▼ SMC 1264/17, these medicines will not be included on the Grampian Joint Formulary for the indications in question. **FTeam**

The following SMC accepted medicines have not been processed within a 60-day timescale:

- SMC 1252/17 Aprepitant (Emend®) – submission expected
- SMC 1256/17 Cilodex® (ciprofloxacin/dexamethasone)
- SMC 1254/17 Glycopyrronium (Sialanar®)
- SMC 1240/17 Nivolumab (Opdivo®) ▼ - submission expected
- SMC 1239/17 Pembrolizumab (Keytruda®) ▼ - submission expected
- SMC 1250/17 Ustekinumab (Stelara®) ▼ - submission received

Local advice for these medicines and indications will be included in the July 2017 decisions as **'Not routinely available as local implementation plans are being developed or the ADTC is waiting for further advice from local clinical experts.'** **FTeam**

SMC 1253/17 - Dolutegravir 10mg, 25mg, 50mg film-coated tablets (Tivicay®) ▼

There were no declarations of interest recorded in relation to this product.

The Group considered the abbreviated SMC advice for dolutegravir that includes new strength tablets, 10mg and 25mg, and a licence extension to allow use of all three strength (10mg, 25mg and 50mg) in children aged 6 years to less than 12 years.
Dolutegravir 50mg is included on the formulary for the treatment of HIV in adults and adolescent above 12 years of age as per SMC 961/14.

The Group accepted the extension to licence and additional strength tablets of dolutegravir to the formulary without the need for a full submission. Acceptance will bring use in line with current practice for patients 12 years and over.

SMC 1253/17 - Dolutegravir 10mg, 25mg, 50mg film-coated tablets (Tivicay®) ▼ is routinely available in line with national guidance (SMC 1253/17).
Indication under review: in combination with other anti-retroviral medicinal products for the treatment of Human Immunodeficiency Virus (HIV) infected children aged >6 to 12 years of age.
SMC has previously accepted dolutegravir 50mg film-coated tablets for use in combination with other anti-retroviral medicinal products for the treatment of HIV infected adults and adolescents above 12 years of age.
This advice takes account of the benefits of a patient access scheme (PAS) that improves the cost-effectiveness of dolutegravir and is contingent upon the continuing availability of the patient access scheme in NHS Scotland or a list price that is equivalent or lower. It was classified 1b - available for restricted use under specialist supervision and 8b - recommended for hospital use only. Treatment should be prescribed by physicians experienced in the management of paediatric HIV infection. **FTeam**

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	SMC 1255/17 – Saxagliptin/dapagliflozin fixed-dose combination tablet	
	There were no declarations of interest recorded in relation to this product.	
	The Group agreed that as one of the components, dapagliflozin, is not recommended for use in NHS Grampian and the other, saxagliptin, is only recommended for use in a small niche of patients, the fixed-dose combination tablet, Qtern® ▼, will not be included on the formulary.	
	SMC 1255/17 - Qtern® ▼ (5mg/10mg film-coated tablets (saxagliptin/dapagliflozin)) is not routinely available as there is a local preference for an alternative medicine. **Indication under review: in adults aged 18 years and older with type 2 diabetes mellitus:** **- to improve glycaemic control when metformin and/or sulphonylurea and one of the monocomponents of Qtern® ▼ do not provide adequate glycaemic control,** **- when already being treated with the free combination of dapagliflozin and saxagliptin** **Restriction: for use in combination with metformin when the use of a sulphonylurea is inappropriate.** **In patients for whom this combination is appropriate, saxagliptin/dapagliflozin (Qtern ▼) offers a single tablet at a lower cost per dose compared with the individual components.** **It was classified 2a – approved by the SMC but currently not recommended for use in NHS Grampian.**	**FTeam**
11.	**GENERAL INFORMATION FROM SMC JULY 2017 – NIL OF NOTE**	
12.	**DOCUMENTS FOR INFORMATION**	
	Items 12.1 (Drug Safety Update June 2017), 12.2 (Patient Safety Alert – Withdrawing insulin from pen devices), 12.3 and 12.4 (Minutes of Medicines Guidelines and Policies Group, April and May 2017) were noted.	
13.	**AOCB**	
	INCRELEX® ▼	
	There were no declarations of interest recorded in relation to this product.	
	The Group reviewed the late submission emailed the day before the meeting.	
	Dr Sun discussed the use of mecasermin injection in primary insulin-like growth factor-1 deficiency (IGFD).	
	The Group noted: • mecasermin 10mg/mL solution for injection (Increlex®) ▼ is an orphan medicine (calculated prevalence less than 2 per 10,000 EU population) licensed by the EMA under 'exceptional circumstances'[2] • the dose is individualised for each patient. Each vial is only stable for 30 days once opened so the minimum cost per 30 days is £605 (£726 inc VAT). At maximum dose, 0.12mg/kg BD, for a 70kg patient the cost for 30days increases to £7,865 (£9,438 inc VAT). • treatment is long-term and costs will increase as the patients weight increases • hypoglycaemia is a very common side-effect. If hypoglycaemia occurs at recommended doses, despite adequate food intake, the dose should be reduced. • the safety profile remains under close scrutiny because at the time of licensing the available safety data was limited to 76 subjects with severe primary IGFD. Due to the rarity of the condition, the number of patients for whom long-term data are available is still very limited.	

[2] A type of marketing authorisation granted to medicines where the applicant is unable to provide comprehensive data on the efficacy and safety under normal conditions of use, because the condition to be treated is rare or because collection of full information is not possible or is unethical.

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	• patients should be entered on the IGFD Register, adverse events should be reported through the Yellow Card Scheme as well as the IGFD Registry • there are no other treatment options, Increlex® ▼ is not a growth hormone treatment • use will be in line with the guidance formulated by the UK IGF-1 User's Group The Group accepted the restricted local need for mecasermin solution for injection. Due to the rarity of IGFD, prescribing of mecasermin is restricted to physicians experienced in the diagnosis and management of growth disorders in children and adolescents. **SMC 563/09 - Mecasermin 10mg/mL solution for injection (Increlex®) ▼ is routinely available in line with National guidance (SMC 563/09).** **Indication under review: for the long-term treatment of growth failure in children and adolescents with severe primary insulin-like growth factor-1 deficiency (primary IGFD).** **Mecasermin significantly improved mean height velocity, mean height velocity standard deviation (SD) score and mean cumulative change in height SD score for at least 6 years. Serious adverse effects including hypoglycaemia and tonsillar hypertrophy are common and long-term safety data are lacking. It was classified 1b - available for restricted use under specialist supervision and 8b - recommended for hospital use only. Treatment should be directed by physicians who are experienced in the diagnosis and management of patients with growth disorders.**	FTeam

THANK YOU AND GOODBYE

The Chairman led members in a heartfelt thank you to two members attending their last meeting.

Caroline Hind in appreciation of her contribution and dedication to the NHS, and excellent work, particularly in relation to her work for Pharmacy and on medicines management groups/projects both locally and nationally. The Pharmacy department will not be the only department to feel the loss of her knowledge and organisational memory. Members wished her a very long and happy retirement.

Dr Sun for her work and commitment to the Formulary Group. A paediatric perspective and comment on decision-making has been a very welcome addition to meetings. Members wished Dr Sun a safe trip and success in her new appointment in China.

DATE OF NEXT MEETING

Tuesday 15 August 2017 starting at 14:30 in the Board Room, Aberdeen Royal Infirmary.

CHAIRMAN'S SIGNATURE _____ **DATE 15 August 2017**