Minutes of the SMC Committee Meeting

Tuesday 02 May 2023

Present:	Dr Scott Muir (Chair) Ms Jane Browning Mr Graeme Bryson Dr Paul Catchpole Ms Alison Culpan Dr Jane Goddard Ms Fiona Green Ms Linda Gunn Dr Roger Hardman Dr Jonathan Hicks Ms Alex Jones Mrs Jennifer Laskey Dr Catriona McMahon Mr Robin McNaught Dr David Montgomery Dr Emma Morrison Dr Paul Neary Dr Robert Peel Dr Joanne Renton Mr Simon Shepherd Ms Carla Verschueren
Observers:	Ms Irene Fazakerley
In Attendance:	Mrs Corinne Booth Ms Ailene Botfield Ms Ailsa Brown Mr Daniel Cairns Mrs Jennifer Dickson Mrs Mairi McConnochie Mrs Pauline McGuire Mrs Fiona McTaggart Ms Rosie Murray Mr Richard O'Connell Ms Yvonne Semple Mrs Catherine Tait

	Mrs Susan Whiston Ms Helen Wright
Apologies:	Mr Calum Adams Mr Andrew Bone Professor James Dear Mr Michael Dickson Mrs Sharon Hems Mrs Christine Hepburn Mr Philip Korsah Mr Scott Mahony Dr Graham Scotland Professor Alison Strath

1.	**Welcome and Apologies for Absence**
1.1	The Chairman welcomed members to the meeting and apologies for absence were noted.
1.2	Welcome to the following observers: Nothing to report.
1.3	Thank you and goodbye Nothing to report.
2.	**Declarations of Interest**
2.1	The Chairman reminded members to declare interests in the products to be discussed and the comparator medicines as noted on the assessment reports.
3.	**Minutes of the Previous Meeting (Tuesday 04 April 2023)**
3.1	The minutes of the SMC meeting held on Tuesday 04 April 2023were accepted as an accurate record of the meeting.
4	**Matters Arising**
4.1	**Deferred Advice**
	Nothing to report.
4.2	**Amended advice**
	patiromer (Veltassa) Vifor Fresenius Medical Care Renal Pharma UK Ltd SMC2568 Minor amendments have been made to the Detailed Advice Document for patiromer (Veltassa), for the treatment of treatment of hyperkalaemia in adults. The DAD was published on Monday 10 April 2023.
5	**Chairman's Business**
5.1	Nothing to report.

6.	**NDC ASSESSMENT REPORTS**
	FULL SUBMISSIONS
6.1	<u>metreleptin powder for solution for injection (Myalepta) Amryt Pharmaceuticals DAC SMC2559</u> No interests were declared in relation to this product/comparator medicines. Representatives of the submitting company were invited to the committee table to respond to specific queries regarding this submission, comment on matters of factual accuracy and provide clarification on any outstanding issues. Representatives of the Patient Group were invited to the committee table to respond to specific queries regarding the Patient Group submission, and provide clarification on any outstanding issues. The NDC Chairman provided an overview of the assessment, draft advice, expert comments, revised data/analysis, and comments received from the company. A member of the Public Involvement Team presented a Patient Group submission from Lipodystrophy UK. Detailed discussion followed and key points of the assessment were agreed. Indication under review: as an adjunct to diet as a replacement therapy to treat the complications of leptin deficiency in lipodystrophy (LD) patients with: • confirmed congenital generalised LD (Berardinelli-Seip syndrome) or acquired generalised LD (Lawrence syndrome) in adults and children 2 years of age and above. • confirmed familial partial LD or acquired partial LD (Barraquer-Simons syndrome), in adults and children 12 years of age and above for whom standard treatments have failed to achieve adequate metabolic control. The SMC advice will be published on the SMC website on Monday 12 June 2023.
6.2	<u>olipudase alfa powder for concentrate for solution for infusion (Xenpozyme) (ASMD) Sanofi SMC2560</u> No interests were declared in relation to this product/comparator medicines. Representatives of the submitting company were invited to the committee table to respond to specific queries regarding this submission, comment on matters of factual accuracy and provide clarification on any outstanding issues. Representatives of the Patient Group were invited to the committee table to respond to specific queries regarding the Patient Group submission, and provide clarification on any outstanding issues. The NDC Co-Vice Chair provided an overview of the assessment, draft advice, expert comments, revised data/analysis, and comments received from the company. A member of the Public Involvement Team presented a Patient Group submission from Neimann-Pick UK. Detailed discussion followed and the group concluded its advice for olipudase alfa powder

	(Xenpozyme), for the treatment as an enzyme replacement therapy for the treatment of non-Central Nervous System (CNS) manifestations of Acid Sphingomyelinase Deficiency (ASMD) in paediatric and adult patients with type A/B or type B. The SMC advice will be withheld pending confirmation of the licence and product availability.
6.3	<u>nivolumab 10mg/mL concentrate for solution for infusion (Opdivo) (OSCC) Bristol Myers Squibb SMC2519</u> No interests were declared in relation to this product/comparator medicines. Representatives of the submitting company were invited to the committee table to respond to specific queries regarding this submission, comment on matters of factual accuracy and provide clarification on any outstanding issues. Representatives of the Patient Group were invited to the committee table to respond to specific queries regarding the Patient Group submission, and provide clarification on any outstanding issues. The NDC Co-Vice Chair provided an overview of the assessment, draft advice, expert comments, revised data/analysis, and comments received from the company. A member of the Public Involvement Team presented a Patient Group submissions from Ochre, Heartburn Cancer UK and Guts UK. Detailed discussion followed and, after a vote of the members, it was decided that nivolumab (Opdivo), should be accepted for use within NHSScotland. Indication under review: in combination with fluoropyrimidine- and platinum-based combination chemotherapy for the first-line treatment of adult patients with unresectable advanced, recurrent or metastatic oesophageal squamous cell carcinoma (OSCC) with tumour cell programmed death ligand 1 (PD-L1) expression ≥1%. Addition of nivolumab to fluoropyrimidine- and platinum-based combination chemotherapy significantly increased overall and progression-free survival in patients receiving first-line treatment for advanced, recurrent or metastatic OSCC with PD-L1 expression ≥1%. This advice applies only in the context of approved NHSScotland Patient Access Scheme (PAS) arrangements delivering the cost-effectiveness results upon which the decision was based, or PAS/ list prices that are equivalent or lower. This advice takes account of the views from a Patient and Clinician Engagement (PACE) meeting. The SMC advice will be published on the SMC website on Monday 12 June 2023.
6.4	<u>polatuzumab vedotin powder for concentrate for solution with infusion (Polivy) Roche Producst Ltd SMC2525</u> No interests were declared in relation to this product/comparator medicines. Representatives of the submitting company were invited to the committee table to respond to specific queries regarding this submission, comment on matters of factual accuracy and provide clarification on any outstanding issues.

	The NDC Co-Vice Chair provided an overview of the assessment, draft advice, expert comments, revised data/analysis, and comments received from the company. A member of the Public Involvement Team presented a Patient Group submission from Lymphoma Action. Detailed discussion followed and, after a vote of the members, it was decided that polatuzumab vedotin (Polivy), should be accepted for restricted use within NHSScotland. Indication under review: in combination with rituximab, cyclophosphamide, doxorubicin, and prednisone (R-CHP) for the treatment of adult patients with previously untreated diffuse large B-cell lymphoma (DLBCL). **SMC restriction:** patients with an International Prognostic Index (IPI) score of 2 to 5 Polatuzumab vedotin, in combination with R-CHP, resulted in a statistically significant improvement in investigator-assessed progression-free survival compared with rituximab, cyclophosphamide, vincristine, doxorubicin and prednisone (R-CHOP). This advice applies only in the context of an approved NHSScotland Patient Access Scheme (PAS) arrangement delivering the cost-effectiveness results upon which the decision was based, or a PAS/ list price that is equivalent or lower. This advice takes account of the views from a Patient and Clinician Engagement (PACE) meeting. The SMC advice will be published on the SMC website on Monday 12 June 2023.
7.	**SMC User Group Forum (UGF)**
7.1	The SMC UGF met on Tuesday 18 April 2023, key topics discussed were: • Progress on the UK Innovative Licensing and Access Pathway (ILAP) process and working in a more efficient way. • Update on partnership working and positive aspects with the National Institute for Health and Care Excellence (NICE) and SMC. • Sustainability in relation to medicines utilisation. • Yvonne Semple provided an update in her new role over the past five months and there was discussion on future UGF agenda with particular focus on key areas which was well received.
8.	**Forthcoming Submissions**
8.1	Noted
9.	**Area Drug & Therapeutics Committee (ADTC) Issues**
9.1	Nothing to report
10.	**Any Other Business**

10.1	Nothing to report
11.	**Closed Session**
	NON SUBMISSIONS
11.	Nothing to report.
12.	**Any Other Business in Closed Session**
12.1	Nothing to report.
12.1	**Any Other Business in closed session** **Update on medicines accepted via streamlined approach** Following review by the SMC executive, SMC advice will be issued in confidence to NHS Boards on Friday 05 May 2023, and published on the SMC website on Monday 12 June 2023. **FULL** treosulfan powder for solution for infusion (Trecondi) Medac Pharma LLP SMC2527 Accepted for restricted use within NHSScotland, in combination with fludarabine as part of conditioning treatment prior to allogeneic haematopoietic stem cell transplantation (alloHSCT) in adult patients with malignant and non-malignant diseases, and in paediatric patients older than one month with malignant diseases. pembrolizumab concentrate for solution for infusion (Keytruda) (TNBC) Merck Sharp & Dohme (UK) Ltd SMC2538 Accepted for use within NHSScotland, in combination with chemotherapy as neoadjuvant treatment, and then continued as monotherapy as adjuvant treatment after surgery, for the treatment of adults with locally advanced, or early stage triple-negative breast cancer (TNBC) at high risk of recurrence. **ABBREVIATED** upadacitinib 15mg, 30mg and 45mg prolonged-release tablets (Rinvoq) (CROHN'S) AbbVie UK Limited SMC2575 Accepted for use within NHSScotland, for the treatment of adult patients with moderately to severely active Crohn's disease (CD) who have had an inadequate response, lost response or were intolerant to either conventional therapy or a biologic agent, or for whom such therapies are not advisable.
13.	**Date of the Next Meeting**
13.1	The date of the next meeting was confirmed as Tuesday 06 June 2023.