Minutes of the SMC Committee Meeting

Tuesday 07 January 2025

Present:	Dr Scott Muir (Chair) Mrs Kathleen Boyd Ms Jane Browning Mr Graeme Bryson Ms Sharon Cowell-Smith Ms Alison Culpan Professor James Dear Dr Jane Goddard Ms Fiona Green Dr Roger Hardman Dr Jonathan Hicks Ms Alex Jones Mrs Jennifer Laskey Mr Anthony McDavitt Mr Mike McLean Dr Catriona McMahon Mr Robin McNaught Dr Emma Morrison Dr Robert Peel Dr Joanne Renton Dr Graham Scotland Professor Alison Strath Professor Marc Turner
Observers:	Ms Irene Fazakerley Meryl Heggeland Claire Henderson-Hughes Rachael Kelly
In Attendance:	Mrs Corinne Booth Ms Ailene Botfield Ms Ailsa Brown Mr Daniel Cairns Mrs Jennifer Dickson

	Mr James Drinkell Mr Roy Foot Ms Patricia Hannam Mrs Sharon Hems Mrs Christine Hepburn Mr Scott Mahony Mrs Mairi McConnochie Mrs Pauline McGuire Mrs Fiona McTaggart Ms Rosie Murray Mr Richard O'Connell Ms Yvonne Semple Mrs Catherine Tait
Apologies:	Mr Andrew Bone Dr Paul Catchpole Ms Fiona Davies Dr Colm Doody Ms Linda Gunn Dr Craig Harrow Mr Philip Korsah Ms Eileidh McIntosh Dr Paul Neary Mr Simon Shepherd Ms Caroline Whitworth

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: **Claire Henderson-Hughes**, NDC Member **Rachael Kelly**, Formulary and Clinical Effectiveness Pharmacist, NHS Lanarkshire **Cecilia Onyeka Okolo**, Health Economist, Scottish Health Technology Group, Healthcare Improvement Scotland
1.3	Thank you and goodbye **Fiona Green, Consultant Diabetologist, NHS Dumfries & Galloway** whose term has ended. We wish to thank Fiona for her commitment and input to SMC over the past 8 years (5 years NDC / 3 years SMC).
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 03 December 2024**
3.1	The minutes of the SMC meeting held on Tuesday 03 December 2024 were accepted as an accurate record of the meeting.
4	**Matters Arising**
4.1	**Deferred Advice**
	Nothing to report.
4.2	**Amended advice**
	Nothing to report.
5	**Chairman's Business**
5.1	SMC2492 atezolizumab (Tecentriq) There has been a minor amendment to the wording of the early-stage non-small cell lung cancer (NSCLC) Marketing Authorisation for atezolizumab (Tecentriq), to align with the EU Marketing Authorisation as part of the Windsor Framework. The DAD will not been amended, however, NHS Boards have been informed, for awareness. daratumumab (Darzalex) The Marketing Authorisation for daratumumab (Darzalez) has been extended to include use, in combination with bortezomib, lenalidomide and dexamethasone, for the treatment of adult patients with newly diagnosed multiple myeloma who are eligible for autologous stem cell transplant. SMC has previously issued advice for daratumumab in combination with bortezomib, thalidomide and dexamethasone, for the treatment of adult patients with newly diagnosed multiple myeloma who are eligible for autologous stem cell transplant (SMC2302 daratumumab (Darzalex)). SMC will not review this minor change to the indication.

6.	**NDC ASSESSMENT REPORTS**
	FULL SUBMISSIONS
6.1	<u>lecanemab concentrate for solution for infusion (Leqembi) Eisai SMC2700</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 Patient Group submissions from Alzheimer's Scotland, Alzheimer's Research UK and Dementia UK. Detailed discussion followed and, after a vote of the members, it was decided that lecanemab (Leqembi) should **not be recommended** for use in NHS Scotland. Indication under review: for the treatment of mild cognitive impairment and mild dementia due to Alzheimer's disease in adult patients that are apolipoprotein E ε 4 (ApoEε4) heterozygotes or non-carriers. In a randomised, double-blind, phase III study, lecanemab reduced the cognitive and functional decline associated with early Alzheimer's disease compared with placebo at 18 months. The submitting company's justification of the treatment's cost in relation to its health benefits was not sufficient and in addition the company did not present a sufficiently robust clinical and economic analysis to gain acceptance by SMC. The SMC advice will be published on the SMC website on Monday 10 February 2025.
6.2	<u>cabotegravir prolonged-release suspension for injection and film-coated tablets (Apretude) ViiV Healthcare UK Ltd SMC2718</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 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 Patient Group submissions from National Aids Trust and Waverley Care. Detailed discussion followed and, after a vote of the members, it was decided that cabotegravir (Apretude) should be **accepted for restricted** use in NHS Scotland. Indication under review: Cabotegravir prolonged-release injection: in combination with safer sex practices for pre-exposure prophylaxis (PrEP) to reduce the risk of sexually acquired HIV-1 infection in high-risk adults and adolescents, weighing at least 35 kg. Cabotegravir tablets: in combination with safer sex practices for short term pre-exposure prophylaxis (PrEP) to reduce the risk of sexually acquired HIV-1 infection in high-risk adults and adolescents, weighing at least 35 kg. Cabotegravir tablets may be used as: • oral lead-in to assess tolerability of cabotegravir prior to administration of long acting cabotegravir injection. • oral PrEP for individuals who will miss planned dosing with cabotegravir injection. **SMC restriction:** Adults and adolescents (weighing at least 35kg) at high risk of sexually acquired HIV who are eligible for PrEP, including oral PrEP, but for whom oral PrEP is not appropriate to meet their HIV prevention needs. Cabotegravir was superior to daily oral tenofovir disoproxil fumarate/emtricitabine in the reduction of incident HIV acquisitions in a phase IIb/III study in men who have sex with men and transgender women (HPTN 083) and in a phase III study in cisgender women (HPTN 084) at high risk of acquiring human immunodeficiency virus (HIV). 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. The SMC advice will be published on the SMC website on Monday 10 February 2025.
6.3	<u>cemiplimab concentrate for solution for infusion (Libtayo) Regeneron UK Ltd SMC2719</u> A personal financial specific declaration of interest was recorded 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. Detailed discussion followed and, after a vote of the members, it was decided that cemiplimab (Libtayo) should be **accepted** for use in NHS Scotland. Indication under review: as monotherapy for the treatment of adult patients with recurrent or metastatic cervical cancer and disease progression on or after platinum-based chemotherapy.

	In a phase III study, cemiplimab monotherapy resulted in a significant improvement in overall survival, compared with investigator's choice of chemotherapy. 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 10 February 2025.
7.	**Forthcoming Submissions**
7.1	Noted
8.	**Area Drug & Therapeutics Committee (ADTC) Issues**
8.1	Nothing to report.
9.	**Any Other Business**
9.1	Nothing to report.
	Closed Session
10.	**Any Other Business in Closed Session**
10.1	Nothing to report.
11.	**Update on medicines accepted via streamlined approach**
	FULL SUBMISSIONS
11.1	<u>netarsudil plus latanoprost eye drops solution (Roclanda) Santen UK Limited SMC2720</u> **Accepted for restricted** use within NHSScotland. **Indication under review:** for the reduction of elevated intraocular pressure (IOP) in adult patients with primary open-angle glaucoma or ocular hypertension for whom monotherapy with a prostaglandin or netarsudil provides insufficient IOP reduction. **SMC restriction:** for use in patients for whom treatment with a prostaglandin analogue alone provides insufficient IOP reduction, only if: • the patient has then tried a fixed-dose combination treatment and it has not sufficiently reduced IOP, or • a fixed-dose combination treatment containing beta-blockers is unsuitable In a phase III study, netarsudil plus latanoprost was non-inferior to a prostaglandin analogue plus beta-blocker in mean IOP at week 2, week 6 and month 3.

	The SMC advice will be published on the SMC website on Monday 10 February 2025.
11.2	fenfluramine oral solution (Fintepla) UCB Pharma Ltd SMC2723 **Accepted for restricted** use within NHSScotland. **Indication under review:** treatment of seizures associated with Lennox-Gastaut syndrome as an add-on therapy to other anti-epileptic medicines for patients 2 years of age and older. **SMC restriction:** patients whose seizures have not been controlled after trying two or more anti-epileptic medicines. In a randomised, double-blind, phase III study, fenfluramine significantly reduced drop seizure frequency in patients (aged 2 to 35 years) with Lennox-Gastaut syndrome that was inadequately controlled by current anti-epileptic medicines, compared with placebo. 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. The SMC advice will be published on the SMC website on Monday 10 February 2025.
	ABBREVIATED SUBMISSIONS
11.3	durvalumab 50 mg/mL concentrate for solution for infusion (Imfinzi) AstraZeneca UK Ltd SMC2734 **Accepted** for use within NHSScotland. **Indication under review:** in combination with etoposide and either carboplatin or cisplatin for the first-line treatment of adults with extensive-stage small cell lung cancer (ES-SCLC). Durvalumab offers an additional treatment choice in the therapeutic class of PD-1 / PD-L1 (Programmed cell death protein 1 / death ligand 1) inhibitors. Another PD-1 / PD-L1 inhibitor was accepted for use under the end of life and orphan process. 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. The SMC advice will be published on the SMC website on Monday 10 February 2025.
11.4	olaparib 150 mg film-coated tablets (Lynparza) AstraZeneca UK Limited SMC2737 **Accepted** for use within NHSScotland. **Indication under review:** monotherapy for the treatment of adult patients with germline *BRCA1/2*-mutations, who have HER2 negative locally advanced or metastatic breast cancer. Patients should have previously been treated with an anthracycline and a taxane in the (neo)adjuvant or metastatic setting unless patients were not suitable for these treatments.

	Patients with hormone receptor (HR)-positive breast cancer should also have progressed on or after prior endocrine therapy, or be considered unsuitable for endocrine therapy. Olaparib offers an additional treatment choice in the therapeutic class of poly (ADP-ribose) polymerase (PARP) inhibitors. Another medicine within this therapeutic class has been accepted for use via the end of life medicine process. 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. The SMC advice will be published on the SMC website on Monday 10 February 2025.
12.	**Date of the Next Meeting**
12.1	The date of the next meeting was confirmed as Tuesday 04 February 2025.