

ADTC(M) 22/02  
Minutes 12 - 22

## NHS GREATER GLASGOW AND CLYDE

### Minutes of the Meeting of the Area Drugs and Therapeutics Committee held on Monday 13 June 2022 at 2.00pm via Microsoft Teams

#### PRESENT

Dr Scott Muir (in the Chair)

Mr Roy Foot	Mr Alister MacLaren
Ms Yvonne Clark	Mrs Elaine McIvor
Dr Roger Hardman	Mrs Mairi-Anne McLean
Dr Mark Fawcett	Dr Stefanie Lip
Dr Maureen Byrne	Ms Fiona Thomson
Ms Aileen Muir	Ms Audrey Thompson
Mrs Janice Watt	Dr Judith Simpson
Prof Gerry McKay	Dr Beth White

#### IN ATTENDANCE

Ms Amy Harkins	..	Pharmacist (Observer)
Mrs Louise Russell	..	Interim Secretariat Manager (Minute)
Ms Ray Howard	..	Secretariat Officer (Observer)
Ms Beata Watson	..	Secretariat Officer (Observer)

			ACTION BY
<b>12.</b>	<b>CHAIR'S STATEMENT</b>		
	<p>The Chair reminded members that papers and proceedings related to SMC advice were, in some cases, confidential, and should not be disclosed before the relevant embargo dates.</p> <p>Members were reminded to make relevant declarations of interest in line with Board policy.</p> <p>Members were advised not to speak with members of the press on ADTC business but to refer such enquiries to the Board Press Liaison Office.</p> <p><b>NOTED</b></p>		

			ACTION BY
<b>13.</b>	<b>WELCOME AND APOLOGIES</b>		
	<p>The Chair welcomed those present to the June Meeting of the Area Drugs and Therapeutics Committee. The Chair welcomed Dr Mark Fawcett to his first meeting. Dr Fawcett had joined the Committee as a GP Subcommittee representative.</p> <p>Apologies for absence were intimated on behalf of Dr Raymund White, Ms Gail Caldwell, Dr Gordon Forrest and Mr Alex Crighton.</p> <p><b><u>NOTED</u></b></p>		
<b>14.</b>	<b>MINUTES OF PREVIOUS MEETING</b>		
	<p>The Committee considered the minute of the meeting held on Monday 21 February 2022 [Paper No. ADTC(M)22/01] and were content to accept this as an accurate record.</p> <p><b><u>APPROVED</u></b></p>		
<b>15.</b>	<b>MATTERS ARISING</b>		
	<p>There were no matters arising.</p> <p><b><u>NOTED</u></b></p>		
<b>16.</b>	<b>NEW MEDICINES FOR CONSIDERATION</b>		
<b>(I)</b>	<b><u>REPORT ON SMC PRODUCT ASSESSMENTS</u></b>		
	<p>Members were asked to declare any interests specific or non-specific, personal or non-personal, on any of the drugs being discussed on an individual basis.</p> <p>No declarations of interest were made.</p> <p><i>See Appendix 1 for summarised decisions.</i></p>		
<b>(II)</b>	<b>WEST OF SCOTLAND CANCER NETWORK PRESCRIBING ADVISORY SUBGROUP REPORTS</b>		
	<b>a) MARCH 2022</b>		

			<b>ACTION BY</b>
	The Committee noted the West of Scotland Cancer Network Prescribing Advisory Subgroup Summary of Advice for March 2022.		
	<b>b) JUNE 2022</b>		
	The Committee noted the West of Scotland Cancer Network Prescribing Advisory Subgroup Summary of Advice for June 2022.  <b><u>NOTED</u></b>		
<b>17.</b>	<b>FORMULARY MANAGEMENT POLICY</b>		
	The Committee noted the paper 'Formulary Management Policy' presented by Mr Roy Foot.  Mr Foot informed the Committee that the policy incorporated separate process and guidance documents into one document. Mr Foot reported that the document included general principles, criteria for the preferred list, which had not changed, appeal information and management of interests.  The Committee were asked to review the document and submit comments to the Secretary by 20 <sup>th</sup> June 2022 prior to the document being uploaded to the GG&C website.  <b><u>NOTED</u></b>		<b>All</b>
<b>18.</b>	<b>ADTC SUBCOMMITTEE UPDATES</b>		
<b>a)</b>	<b>PRESCRIBING INTERFACE SUBCOMMITTEE</b>		
	No update since the last meeting.  <b><u>NOTED</u></b>		
<b>b)</b>	<b>SAFER USE OF MEDICINES SUBCOMMITTEE</b>		
	Prof McKay provided an update on behalf of the Safer Use of Medicines Subcommittee. The next meeting was scheduled for 21 <sup>st</sup> June 2022.  In response to a question regarding the work that the ADTCC requested in relation to Best Practice of Valproate Prescribing, the Committee note that work was ongoing. A GGC group was in		

			<b>ACTION BY</b>
	<p>the process of being co-ordinated and work was being carried out to identify patients. The Committee noted that the Risk Acknowledgement Form was being reviewed and updates would be made to the electronic form. The Committee noted issues had been highlighted in relation to the form being completed. A Mental Health audit had been carried out and results were awaited. Work would take place to review the lists and prescribing data and then a targeted approach would be taken. The Committee noted that nominations from each Board had been requested by ADTCC to be involved in the process of establishing a new learning system. The Committee noted that Craig Heath would represent GGC for neurology and another nomination would be sought from Mental Health services. The Committee noted that a cohort of patients would be identified by the Prescribing Teams.</p> <p>The Committee noted the update provided.</p> <p><b><u>NOTED</u></b></p>		
<b>c)</b>	<b>NON-MEDICINES UTILIATION SUBCOMMITTEE</b>		
	<p>Mrs Mairi-Anne McLean provided a verbal update on behalf of the Non-Medicines Utilisation Subcommittee.</p> <p>The Committee last met in May 2022. Mrs McLean informed the Committee that a review of the Wound Formulary would be taking place in due course.</p> <p>The Committee noted the update provided.</p> <p><b><u>NOTED</u></b></p>		
<b>d)</b>	<b>MEDICINES UTILISATION SUBCOMMITTEE</b>		
	<p>Mr Roy Foot provided an update on behalf of the Medicines Utilisation Subcommittee.</p> <p>The Medicines Utilisations Subcommittee continued to review a number of guidelines.</p> <p>Discussions had taken place regarding the re-introduction of Medicines Utilisation Reports, pending capacity. The Committee noted that the content in the reports would be broad however may cover topics such as biologics in gastroenterology and monoclonal antibodies in asthma and prescribing variation in different areas. Mr Foot sought the opinion of ADTC members regarding the re-introduction of reports which could be submitted</p>		

			<b>ACTION BY</b>
	to the Committee as part of its six monthly update. Detailed reports or any specific work would be carried out by the Clinical Effectiveness Team.		
	The Committee noted the update provided and were content to support the re-introduction of Medicines Utilisation Reports.		
	<b><u>NOTED</u></b>		
<b>e)</b>	<b>COMMUNICATIONS SUBCOMMITTEE</b>		
	Mrs Elaine Mclvor provided an update on behalf of the Communications Subcommittee. The Subcommittee continued to meet every 4 weeks.		
	Mrs Mclvor reported that the first blogs on Opioid Safety and Pain had been published. Insulin Safety and DOAC blogs are also in development. Mrs Mclvor highlighted in particular a Yellow Card Scheme blog from April 2022. She reported that a Yellow Card Scheme representative was due to attend GGC grand rounds in October 2022.		
	The Committee noted the update provided.		
	<b><u>NOTED</u></b>		
<b>f)</b>	<b>PATIENT GROUP DIRECTIVE SUBCOMMITTEE</b>		
	As there was no representation from the Patient Group Directive Subcommittee present, this item was deferred to a future meeting.		
	<b><u>NOTED</u></b>		
<b>g)</b>	<b>ANTIMICROBIAL SUBCOMMITTEE</b>		
	Dr Beth White provided an update on behalf of the Antimicrobial Subcommittee		
	Dr White highlighted that there had been a 30% reduction in antibiotic use in Primary Care. The Committee noted that Temocillin use had reduced, however there was significant use of Meropenem and Piperacillin-tazobactam which was being monitored. Some work was being carried out in relation to prescribing of Gentamicin on HEPMA and in relation to reducing duration of oral antibiotics.		

			<b>ACTION BY</b>
	The Committee noted the update provided.		
	<b><u>NOTED</u></b>		
<b>19.</b>	<b>ADTC COLLABORATIVE UPDATE</b>		
	Ms Clark provided a verbal update on the ADTC Collaborative.		
	Ms Clark informed the Committee that the ADTC Collaborative Newsletter was due to be reinstated.		
	Ms Clark provided an update on 'Once for Scotland' which was looking at priority pieces of work. Ms Clark encouraged members to submit any ideas for pieces of work.		<b>All</b>
	The Chair thanked Ms Clark for the update.		
	<b><u>NOTED</u></b>		
<b>20.</b>	<b>HEPMA UPDATE</b>		
	The Committee noted the paper 'HEPMA Progress Update' [Paper No. 22/08].		
	The Committee noted that Hospital rollout was now complete. The Clinical Reference Group continued to meet and feed in to the ADTC Safer Use of Medicines Subcommittee.		
	The Committee noted the update provided.		
	<b><u>NOTED</u></b>		
<b>21.</b>	<b>AOCB</b>		
	The Chair asked members to raise any other competent business.		
	There was no other business noted.		
	<b><u>NOTED</u></b>		
<b>22.</b>	<b>DATE OF NEXT SCHEDULED MEETING</b>		
	Monday 15 August 2022, at 2pm, via MS Teams.		

## Appendix 1:NHS Greater Glasgow and Clyde New Medicines Decisions

Date of ADTC Decisions: **13/06/2022**

### Abrocitinib

SMC2431

Cibinqo® tablets

#### Indication:

Treatment of moderate-to-severe atopic dermatitis in adults and adolescents 12 years and older who are candidates for systemic therapy.

#### ADTC Discussion points

Another option for atopic dermatitis and strong enthusiasm from local clinicians who note that options for patients who are failing on other agents are needed.

#### ADTC Decision:

Routinely available in line with national guidance

#### Local restrictions on use:

Restricted to specialist use for the treatment of moderate-to-severe atopic dermatitis in patients who have had an inadequate response to an existing systemic immunosuppressant such as ciclosporin, or in whom such treatment is considered unsuitable.

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### Berotralstat

SMC2405

Orladeyo® capsules

#### Indication:

Routine prevention of recurrent attacks of hereditary angioedema (HAE) in adult and adolescent patients aged 12 years and older.

#### ADTC Discussion points

Potential alternative to regular C1 inhibitor infusions and small patient numbers estimated by local experts.

#### ADTC Decision:

Routinely available in line with national guidance

#### Local restrictions on use:

Restricted to specialist use in patients who experience  $\geq$  two clinically significant attacks per month

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### Dapagliflozin

SMC2428

Forxiga® tablets

#### Indication:

In adults for the treatment of chronic kidney disease.

#### ADTC Discussion points

Dapagliflozin is the first in class to have treatment of CKD as an indication, though canagliflozin licence does allow this use within the licensed indication of treating diabetes. Existing guideline will be updated to reflect this SMC advice.

#### ADTC Decision:

Routinely available in line with national guidance

#### Local restrictions on use:

Use in the treatment of chronic kidney disease (CKD) is restricted to specialist initiation in patients with an estimated glomerular filtration rate of  $\geq 25$  to  $\leq 75$  mL/min/1.73m<sup>2</sup> at treatment initiation, who are receiving an angiotensin converting enzyme inhibitor or angiotensin receptor blocker (unless these are not tolerated or contraindicated), and have a urine albumin-creatinine ratio of at least 23mg/mmol and/or type 2 diabetes mellitus.

## Oritavancin

SMC2285

Tenkasi® infusion

### Indication:

Treatment of acute bacterial skin and skin structure infections (ABSSSI) in adults.

### ADTC Discussion points

Local clinicians do not feel there are any advantages over other agents (e.g. Dalbavancin).

### ADTC Decision:

Not routinely available as local clinical experts do not wish to add the medicine to the Formulary at this time or there is a local preference for alternative medicine(s)

### Local restrictions on use:

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## Upadacitinib

SMC2417

Rinvoq® tablets

### Indication:

Treatment of moderate to severe atopic dermatitis in adults and adolescents 12 years and older who are candidates for systemic therapy.

### ADTC Discussion points

New option for atopic dermatitis where experts say would likely be used where dupilumab and baracitinib have failed or are not tolerated (commented by experts that adverse effects on the eye are less prominent with this new agent). Could be incorporated into guidelines, which have only just been recently approved.

### ADTC Decision:

Routinely available in line with national guidance

### Local restrictions on use:

Use for moderate to severe atopic dermatitis is restricted to specialist use in patients who have had an inadequate response to at least one conventional systemic immunosuppressant such as ciclosporin, or in whom such treatment is considered unsuitable.

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## Filgotinib

SMC2467

Jyseleca® tablets

### Indication:

Treatment of adult patients with moderately to severely active ulcerative colitis (UC) who have had an inadequate response with, lost response to, or were intolerant to either conventional therapy or a biologic agent.

### ADTC Discussion points

An alternative JAK inhibitor for ulcerative colitis. Expected to be used followed anti-TNF.

### ADTC Decision:

Routinely available in line with national guidance

### Local restrictions on use:

Restricted to specialist use for the treatment of adult patients with moderately to severely active ulcerative colitis (UC) who have had an inadequate response with, lost response to, or were intolerant to either conventional therapy or a biologic agent

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## Risankizumab

SMC2459

Skyrizi® injection

### Indication:

Alone or in combination with methotrexate (MTX), is indicated for the treatment of active psoriatic arthritis in adults who have had an inadequate response or who have been intolerant to one or more disease-modifying antirheumatic drugs (DMARDs).

### ADTC Discussion points

A new IL-23 inhibitor for PsA which is likely to be used in a 3rd line positioning. Updated guidelines are currently in development in this therapeutic area.

### ADTC Decision:

Routinely available in line with national guidance

### Local restrictions on use:

Use for active psoriatic arthritis is restricted to specialist use in:

- patients whose disease has not responded adequately or who have been intolerant to two previous conventional disease-modifying antirheumatic drug (DMARD) therapies but have not received biologic DMARD therapy (biologic-naïve population);
- patients whose disease has not responded adequately to conventional DMARDs and one or more tumour necrosis factor (TNF) inhibitors (biologic-experienced population); and
- patients in whom TNF inhibitors are contraindicated or not tolerated.

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## Dostarlimab

SMC2404

Jemperli® infusion

### Indication:

Monotherapy for the treatment of adult patients with mismatch repair deficient (dMMR)/microsatellite instability-high (MSI-H) recurrent or advanced endometrial cancer (EC) that has progressed on or following prior treatment with a platinum-containing regimen.

### ADTC Discussion points

Referred to RCAG for regional protocol development.

### ADTC Decision:

Routinely available in line with local or regional guidance

### Local restrictions on use:

Restricted to specialist use in accordance with regional protocol.

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## Fedratinib

SMC2462

Inrebic® capsules

### Indication:

Treatment of disease-related splenomegaly or symptoms in adult patients with primary myelofibrosis, post polycythaemia vera myelofibrosis or post essential thrombocythaemia myelofibrosis who are Janus Associated Kinase (JAK) inhibitor naïve or have been treated with ruxolitinib.

### ADTC Discussion points

Referred to RCAG for regional protocol development.

### ADTC Decision:

Routinely available in line with local or regional guidance

### Local restrictions on use:

Restricted to specialist use in accordance with regional protocol.

## Lenvatinib

SMC2476

Kisplyx® capsules

### Indication:

Treatment of adults with advanced renal cell carcinoma (RCC), in combination with pembrolizumab, as first-line treatment

### ADTC Discussion points

Referred to RCAG for regional protocol development.

### ADTC Decision:

Routinely available in line with local or regional guidance

### Local restrictions on use:

Restricted to specialist use in accordance with regional protocol and subject to a two-year clinical stopping rule.

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## Nivolumab

SMC2429

Opdivo® infusion

### Indication:

Monotherapy for the adjuvant treatment of adult patients with completely resected oesophageal or gastro-oesophageal junction cancer who have residual pathologic disease following prior neoadjuvant chemoradiotherapy.

### ADTC Discussion points

Referred to RCAG for regional protocol development.

### ADTC Decision:

Routinely available in line with local or regional guidance

### Local restrictions on use:

Restricted to specialist use in accordance with regional protocol.

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## Pembrolizumab

SMC2420

Keytruda® infusion

### Indication:

In combination with platinum and fluoropyrimidine based chemotherapy, for the first-line treatment of patients with locally advanced unresectable or metastatic carcinoma of the oesophagus or HER-2 negative gastroesophageal junction adenocarcinoma in adults whose tumours express PD-L1 with a CPS $\geq$ 10.

### ADTC Discussion points

Referred to RCAG for regional protocol development.

### ADTC Decision:

Routinely available in line with local or regional guidance

### Local restrictions on use:

Restricted to specialist use in accordance with regional protocol and subject to a two-year clinical stopping rule.

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## Sacituzumab

SMC2446

Trodelvy® infusion

### Indication:

Treatment of adult patients with unresectable locally advanced or metastatic triple-negative breast cancer (mTNBC) who have received two or more prior lines of systemic therapies, at least one of them given for unresectable locally advanced or metastatic disease.

### ADTC Discussion points

Referred to RCAG for regional protocol development.

### ADTC Decision:

Routinely available in line with local or regional guidance

### Local restrictions on use:

Restricted to specialist use in accordance with regional protocol.

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## Sotorasib

SMC2443

Lumykras® tablets

### Indication:

Monotherapy for the treatment of adult patients with KRAS G12C-mutated, locally advanced or metastatic, non-small cell lung cancer (NSCLC), who have progressed on, or are intolerant to platinum-based chemotherapy and/or anti PD-1/PD-L1 immunotherapy.

### ADTC Discussion points

### ADTC Decision:

Routinely available in line with local or regional guidance

### Local restrictions on use:

Restricted to specialist use in accordance with regional protocol.

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## Venetoclax

SMC2427

Venclyxto® tablets

### Indication:

In combination with obinutuzumab for the treatment of adult patients with previously untreated chronic lymphocytic leukaemia (CLL).

### ADTC Discussion points

Referred to RCAG for regional protocol development.

### ADTC Decision:

Routinely available in line with local or regional guidance

### Local restrictions on use:

Restricted to specialist use in accordance with regional protocol in patients without del (17p)/TP53 mutation who are fit to receive fludarabine, cyclophosphamide and rituximab (FCR) chemo-immunotherapy

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## Venetoclax

SMC2412

Venclyxto® tablets

### Indication:

In combination with a hypomethylating agent for the treatment of adult patients with newly diagnosed acute myeloid leukaemia (AML) who are ineligible for intensive chemotherapy.

### ADTC Discussion points

Referred to RCAG for regional protocol development.

### ADTC Decision:

Routinely available in line with local or regional guidance

### Local restrictions on use:

Restricted to specialist use in accordance with regional protocol.

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## Belimumab

SMC2483

injection in pre injection

### Indication:

In combination with background immunosuppressive therapies for the treatment of adult patients with active lupus nephritis.

### ADTC Discussion points

### ADTC Decision:

Not routinely available as not recommended for use in NHSScotland

### Local restrictions on use:

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## Blinatumomab

SMC2468

Blincyto® infusion

### Indication:

Monotherapy for the treatment of adults with CD19 positive relapsed or refractory B-precursor acute lymphoblastic leukaemia (ALL). Patients with Philadelphia chromosome positive B-precursor ALL should have failed treatment with at least 2 tyrosine kinase inhibitors (TKIs) and have no alternative treatment options.

### ADTC Discussion points

### ADTC Decision:

Not routinely available as not recommended for use in NHSScotland

### Local restrictions on use:

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## Carfilzomib

SMC2484

Kyprolis® infusion

### Indication:

In combination with daratumumab and dexamethasone for the treatment of adult patients with multiple myeloma who have received at least one prior therapy.

### ADTC Discussion points

### ADTC Decision:

Not routinely available as not recommended for use in NHSScotland

### Local restrictions on use:

## Cemiplimab

SMC2489

Libtayo® infusion

### Indication:

As monotherapy for the first-line treatment of adult patients with non-small cell lung cancer (NSCLC) expressing PD-L1 (in  $\geq 50\%$  tumour cells), with no EGFR, ALK or ROS1 aberrations, who have:

- locally advanced NSCLC who are not candidates for definitive chemoradiation, or
- metastatic NSCLC

### ADTC Discussion points

#### ADTC Decision:

Not routinely available as not recommended for use in NHSScotland

#### Local restrictions on use:

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## Daratumumab

SMC2469

Darzalex® injection

### Indication:

Combination with pomalidomide and dexamethasone for the treatment of adult patients with multiple myeloma who have received one prior therapy containing a proteasome inhibitor and lenalidomide and were lenalidomide-refractory, or who have received at least two prior therapies that included lenalidomide and a proteasome inhibitor and have demonstrated disease progression on or after the last therapy.

### ADTC Discussion points

#### ADTC Decision:

Not routinely available as not recommended for use in NHSScotland

#### Local restrictions on use:

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## Givosiran

SMC2470

Givlaari® injection

### Indication:

Treatment of acute hepatic porphyria in adults and adolescents aged 12 years and older.

### ADTC Discussion points

#### ADTC Decision:

Not routinely available as not recommended for use in NHSScotland

#### Local restrictions on use:

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## Ibrutinib

SMC2485

Imbruvica® tablets

### Indication:

In combination with rituximab for the treatment of adult patients with previously untreated chronic lymphocytic leukaemia.

### ADTC Discussion points

#### ADTC Decision:

Not routinely available as not recommended for use in NHSScotland

#### Local restrictions on use:

## Mepolizumab

SMC2490

Nucala® injection

### Indication:

As an add-on treatment for patients aged 6 years and older with relapsing-remitting or refractory eosinophilic granulomatosis with polyangiitis (EGPA).

### ADTC Discussion points

#### ADTC Decision:

Not routinely available as not recommended for use in NHSScotland

#### Local restrictions on use:

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## Mepolizumab

SMC2488

Nucala® injection

### Indication:

Add-on treatment for adult patients with inadequately controlled hypereosinophilic syndrome without an identifiable non-haematologic secondary cause.

### ADTC Discussion points

#### ADTC Decision:

Not routinely available as not recommended for use in NHSScotland

#### Local restrictions on use:

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## Mepolizumab

SMC2491

Nucala® injection

### Indication:

Add-on therapy with intranasal corticosteroids for the treatment of adult patients with severe chronic rhinosinusitis with nasal polyps for whom therapy with systemic corticosteroids and/or surgery do not provide adequate control.

### ADTC Discussion points

#### ADTC Decision:

Not routinely available as not recommended for use in NHSScotland

#### Local restrictions on use:

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## Ruxolitinib

SMC2498

Jakavi® tablets

### Indication:

treatment of:

- patients aged 12 years and older with acute graft versus host disease who have inadequate response to corticosteroids
- patients aged 12 years and older with chronic graft versus host disease who have inadequate response to corticosteroids

### ADTC Discussion points

#### ADTC Decision:

Not routinely available as not recommended for use in NHSScotland

#### Local restrictions on use:

## White birch *betula verrucosa* extract

SMC2471

Itulazax 12 SQ oral lyophilisate

### Indication:

In adult patients for the treatment of moderate-to-severe allergic rhinitis and/or conjunctivitis induced by pollen from the birch homologous group. ITULAZAX is indicated in patients with a clinical history of symptoms despite use of symptom-relieving medication and a positive test of sensitisation to a member of the birch homologous group (skin prick test and/or specific IgE).

### ADTC Discussion points

#### ADTC Decision:

Not routinely available as not recommended for use in NHSScotland

#### Local restrictions on use:

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## Daratumumab

SMC2416

Darzalex® injection

### Indication:

In combination with bortezomib, melphalan and prednisone for the treatment of adult patients with newly diagnosed multiple myeloma who are ineligible for autologous stem cell transplant.

### ADTC Discussion points

#### ADTC Decision:

Not routinely available as not recommended for use in NHSScotland

#### Local restrictions on use:

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## Hydrocortisone

SMC2414

Efmody® MR capsules

### Indication:

Treatment of congenital adrenal hyperplasia (CAH) in adolescents aged 12 years and over and adults.

### ADTC Discussion points

#### ADTC Decision:

Not routinely available as not recommended for use in NHSScotland

#### Local restrictions on use:

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## Ixekizumab

SMC2440

Taltz® pre-filled syringe, pen

### Indication:

Ankylosing spondyloarthritis (radiographic axial spondyloarthritis) Treatment of adult patients with active ankylosing spondylitis who have responded inadequately to conventional therapy. Non-radiographic axial spondyloarthritis Treatment of adult patients with active non-radiographic axial spondyloarthritis with objective signs of inflammation as indicated by elevated C-reactive protein (CRP) and/or magnetic resonance imaging (MRI) who have responded inadequately to nonsteroidal anti-inflammatory drugs (NSAIDs).

### ADTC Discussion points

#### ADTC Decision:

Not routinely available as not recommended for use in NHSScotland

#### Local restrictions on use:

## Ropeginterferon alfa-2b

SMC2421

Besremi® injection

### Indication:

Monotherapy in adults for the treatment of polycythaemia vera without symptomatic splenomegaly.

### ADTC Discussion points

### ADTC Decision:

Not routinely available as not recommended for use in NHSScotland

### Local restrictions on use:

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## Solriamfetol

SMC2419

Sunosi® tablets

### Indication:

To improve wakefulness and reduce excessive daytime sleepiness (EDS) in adult patients with obstructive sleep apnoea (OSA) whose EDS has not been satisfactorily treated by primary OSA therapy, such as continuous positive airway pressure (CPAP).

### ADTC Discussion points

### ADTC Decision:

Not routinely available as not recommended for use in NHSScotland

### Local restrictions on use:

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## Tepotinib

SMC2457

Tepmetko® tablets

### Indication:

treatment of adult patients with advanced non-small cell lung cancer (NSCLC) harbouring mesenchymal-epithelial transition factor gene (MET) exon 14 (METex14) skipping alterations.

### ADTC Discussion points

### ADTC Decision:

Not routinely available as not recommended for use in NHSScotland

### Local restrictions on use:

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## Emtricitabine, tenofovir alafenamide

N/A

Descovy tablets

### Indication:

Pre-exposure prophylaxis to reduce the risk of sexually acquired HIV-1 infection in at-risk men who have sex with men, including adolescents (with body weight at least 35 kg)

### ADTC Discussion points

Noted that this would be appropriate alternative for PrEP in patients who develop renal or bone issues with alternative agents.

### ADTC Decision:

Routinely available in line with local or regional guidance

### Local restrictions on use:

Restricted to specialist use for the pre-exposure prophylaxis to reduce the risk of sexually acquired HIV-1 infection in at-risk men who have sex with men who have renal or bone issues for whom other alternative PrEP options are not suitable.

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## Bempedoic acid

SMC2363

Nilemdo® tablets

### Indication:

Adults with primary hypercholesterolaemia (heterozygous familial and non-familial) or mixed dyslipidaemia, as an adjunct to diet:

- In combination with a statin, or a statin with other lipid-lowering therapies in patients unable to reach low-density lipoprotein cholesterol (LDL-C) goals with the maximum tolerated dose of a statin or
- Alone or in combination with other lipid-lowering therapies in patients who are statin-intolerant, or for whom a statin is contra-indicated.

### ADTC Discussion points

Included in updated GGC Cholesterol Guidelines for use only on the recommendation of lipid clinics. Inclusion in guideline was a pre-requisite of adding to Formulary.

### ADTC Decision:

Routinely available in line with local or regional guidance

### Local restrictions on use:

Restricted to use only on the advice of a lipid specialist in accordance with local guidelines for adults with primary hypercholesterolaemia (heterozygous familial and non-familial) or mixed dyslipidaemia, as an adjunct to diet:

- In patients who are statin intolerant or for whom a statin is contra-indicated
  - and where ezetimibe alone does not appropriately control LDL-C
  - And where proprotein convertase subtilisin/ kexin type 9 (PCSK9) inhibitors are not appropriate
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Nustendi® tablets

**Indication:**

Treatment of adults with primary hypercholesterolaemia (heterozygous familial and non-familial) or mixed dyslipidaemia, as an adjunct to diet:

- in combination with a statin in patients unable to reach LDL-C goals with the maximum tolerated dose of a statin in addition to ezetimibe,
- alone in patients who are either statin-intolerant or for whom a statin is contraindicated, and are unable to reach LDL-C goals with ezetimibe alone
- in patients already being treated with the combination of bempedoic acid and ezetimibe as separate tablets with or without statin.

**ADTC Discussion points**

Included in updated GGC Cholesterol Guidelines for use only on the recommendation of lipid clinics. Inclusion in guideline was a pre-requisite of adding to Formulary.

**ADTC Decision:**

Routinely available in line with local or regional guidance

**Local restrictions on use:**

Restricted to use only on the advice of a lipid specialist in accordance with local guidelines for adults with primary hypercholesterolaemia (heterozygous familial and non-familial) or mixed dyslipidaemia, as an adjunct to diet:

- In patients who are statin intolerant or for whom a statin is contra-indicated
- and where ezetimibe alone does not appropriately control LDL-C
- And where proprotein convertase subtilisin/ kexin type 9 (PCSK9) inhibitors are not appropriate

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**Inclisiran**

SMC2358

Leqvio® injection

**Indication:**

Treatment for adults with primary hypercholesterolaemia (heterozygous familial and non-familial) or mixed dyslipidaemia, as an adjunct to diet:

- in combination with a statin or statin with other lipid lowering therapies in patients who are unable to reach LDL-C goals with the maximum tolerated dose of a statin, or
- alone or in combination with other lipid lowering therapies in patients who are statin intolerant, or for whom a statin is contraindicated.

**ADTC Discussion points**

Included in updated GGC Cholesterol Guidelines for use only on the recommendation of lipid clinics. Inclusion in guideline was a pre-requisite of adding to Formulary.

**ADTC Decision:**

Routinely available in line with local or regional guidance

**Local restrictions on use:**

Restricted to use only on the advice of a lipid specialist in accordance with local guidelines for adults with primary hypercholesterolaemia (heterozygous familial and non-familial) or mixed dyslipidaemia, as an adjunct to diet only in patients at high cardiovascular risk as follows:

- patients with heterozygous familial hypercholesterolaemia (HeFH) and LDL-C  $\geq 5.0$ mmol/L, for primary prevention of cardiovascular events or
  - patients with HeFH and LDL-C  $\geq 3.5$ mmol/L, for secondary prevention of cardiovascular events or
  - patients with high risk due to previous cardiovascular events and LDL-C  $\geq 4.0$ mmol/L or
  - patients with recurrent/polyvascular disease and LDL-C  $\geq 3.5$ mmol/L
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## Ponesimod

SMC2384

Ponvory® tablets

### Indication:

Treatment of adult patients with relapsing forms of multiple sclerosis (RMS) with active disease defined by clinical or imaging features.

### ADTC Discussion points

This is an additional treatment choice in this class of agent. Clinicians are in the process of adding to clinical guideline

### ADTC Decision:

Routinely available in line with national guidance

### Local restrictions on use:

Restricted to specialist use in accordance with local guidelines in patients with relapsing-remitting multiple sclerosis (RRMS) with active disease defined by clinical or imaging features, suitable for or requesting an oral treatment.

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## Liraglutide

SMC2455

Saxenda® injection

### Indication:

as an adjunct to a reduced-calorie diet and increased physical activity for weight management in adult patients with an initial Body Mass Index (BMI) of:

- $\geq 30\text{kg/m}^2$  (obese), or
- $\geq 27\text{kg/m}^2$  to  $<30\text{kg/m}^2$  (overweight) in the presence of at least one weight-related comorbidity such as dysglycaemia (prediabetes or type 2 diabetes mellitus), hypertension, dyslipidaemia or obstructive sleep apnoea.

### ADTC Discussion points

SMC restricted use to specialist service and NHSGGC Weight Management Service does not currently directly prescribe medicines. Requires further discussion to ascertain how the medicine would be initiated, prescribed and reviewed in practice. Noted that may require some service development.

### ADTC Decision:

Not routinely available as local implementation plans are being developed or ADTC is waiting for further advice from local clinical experts - Decision expected by:

12/12/2022

### Local restrictions on use:

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## Relugolix, estradiol, norethisterone

SMC2442

Ryeqo® tablets

### Indication:

Treatment of moderate to severe symptoms of uterine fibroids in adult women of reproductive age.

### ADTC Discussion points

Local clinician feedback suggested that further consultation is required with service prior to implementation. Deferred addition to Formulary to allow that to progress.

### ADTC Decision:

Not routinely available as local implementation plans are being developed or ADTC is waiting for further advice from local clinical experts - Decision expected by:

12/12/2022

### Local restrictions on use:

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