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NHSGG&C(M) 21/01
Minutes: 01- 11

NHS GREATER GLASGOW AND CLYDE

Minutes of the Meeting of the
Area Drugs and Therapeutics Committee
held via Microsoft Teams
on Monday 19th April 2021

PRESENT

Dr Scott Muir (in the Chair)

Mr Roy Foot	Mrs Janice Watt
Mrs Aileen Muir	Mrs Alison Campbell
Ms Yvonne Clark	Dr Gordon Forrest
Dr Beth White	Dr Raymund White
Dr Kay McAllister	Dr Roger Hardman
Mrs Audrey Thompson	Ms Fiona Thomson
Mrs Mairi-Anne McLean	Dr Alexander Crighton

IN ATTENDANCE

Ms Kathrin Greschner		Pharmacist, Medicines Policy & Guidance (observer)
Ms Marie-Louise McColgan		Prescribing Support Pharmacist (observer)
Mrs Louise Russell		Secretariat

			ACTION BY
01.	**CHAIRMAN'S STATEMENT**		
	The Chair reminded members that papers and proceedings relating to SMC advice were, in some cases, confidential and should not be disclosed before the relevant embargo dates. He also reminded members that they should make relevant declarations of interest in line with Board policy. 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.		
02.	**WELCOME AND APOLOGIES**		
	Apologies for absence were intimated on behalf of Mrs Gail Caldwell, Dr Fergus MacLean, Dr Judith Simpson, Mrs Elaine McIvor and Prof Gerry McKay. **NOTED**		

03.	**MINUTES OF PREVIOUS MEETING: 14 DECEMBER 2021**		
	The minutes of the meeting held on Monday 14th December 2021 were approved as an accurate record. **APPROVED**		
04.	**MATTERS ARISING**		
	None. **NOTED**		
05.	**NEW MEDICINES FOR CONSIDERATION**		
	(1) Report on SMC Product Assessments		
	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. No declarations of interest were made. *See Appendix 1 for summarised decisions*		
06.	**ADTC SUBCOMMITTEE UPDATES**		
	The Subcommittee Chairs were asked to update on urgent items of business. Fuller reported would be provided at the next meeting.		
	a. Prescribing Interface Subcommittee		
	Dr Hardman provided an update on behalf of the Prescribing Interface Subcommittee. Dr Hardman reported that three outstanding Shared Care Agreements for melatonin and denosumab had been reviewed and approved, with a 3 year review date. The site had been updated. The Committee noted the update provided. NOTED		
	b. Non-Medicines Utilisation Subcommittee		
	Mrs McLean provided an update on behalf of the Non-Medicines Utilisation Subcommittee. Mrs McLean reported that the Subcommittee had not met recently due to the suspension of committee meetings. The next meeting was arranged to take place in May 2021.		

	Mrs McLean reported that the Subcommittee was still without GP representation. It was suggested that contact could be made with GP's via an advert in the weekly mail to GP practices to raise awareness and attract interest in joining the subcommittee. The Committee noted the update provided. **NOTED**		
	c. Safer Use of Medicines Subcommittee		
	No specific update. The next meeting was scheduled to take place on 20th April 2021. **NOTED**		
	d. Antimicrobial Subcommittee		
	Dr White provided an update on behalf of the Antimicrobial Subcommittee. Dr White reported that temocillin had been removed from the guideline. This resulted in savings during quarter 4. A drive to reduce antibiotic therapy duration continued to take place. The Committee noted the paper "Scottish Health Technology Group (SHTG) Recommendations for Outpatient parenteral antimicrobial therapy (OPAT) services for NHS Scotland: Implications for NHS Greater Glasgow and Clyde". The Committee were asked to consider the paper. **NOTED**		
	e. Medicines Utilisation Subcommittee		
	Dr White informed the Committee that a full update would be provided at the next meeting. **NOTED**		
07.	**ADTC COLLABORATIVE UPDATE**		
	Mr Foot reported that there was an EAMS treatment protocol for Abrocitinib. The dermatology team were aware of this. The Committee noted the update provided. **NOTED**		

08.	**MEDICINAL CANNABIS GUIDANCE FOR PRESCRIBERS**		
	The Committee noted the paper which provided information for prescribers. Mr Foot reported that Epidyolex had been licensed and accepted by SMC and the guidance updated to reflect this. Information had been added in relation to prescribing and recommendations from private clinics. The Committee noted that in addition, Dr Scott Davidson, Deputy Medical Director (Acute), had requested that consultants communicated with the Chief of Medicine prior to carrying out private clinic referrals. The Committee noted that the paper would be taken to the Acute Clinical Governance Committee for information. **NOTED**		
09.	**HEPMA PROGRESS UPDATE**		
	The Committee noted the paper submitted to provide an update on HEPMA progress. Mrs Watt informed the Committee that the full roll out commenced today. She highlighted that pharmacy students had been employed for the process of transcription. Mrs Watt reported that this had been going well. Mrs Watt reported that a Clinical Review Group had been established. The Group reported into the ADTC Safer Use of Medicines Subcommittee. Mrs Watt informed the Committee that the Clinical Review Group had representation from Medicine, Nursing and Pharmacy. The Committee noted the update provided. **NOTED**		
10.	**ANY OTHER BUSINESS**		
	None. **NOTED**		
11.	**DATE AND TIME OF NEXT SCHEDULED MEETING**		
	Monday 14th June 2021, 2pm, Microsoft Teams		

Appendix 1:NHS Greater Glasgow and Clyde New Medicines Decisions

Date of ADTC Decisions: **19/04/2021**

Dapagliflozin

SMC2322

Forxiga® tablets

Indication:

The treatment of symptomatic chronic heart failure with reduced ejection fraction in adult patients.

ADTC Discussion points

ADTC encourage the development of guidance to clarify place in therapy. Prescribing restrictions may be able to be reviewed following approval of these. The introduction of this medicine into practice should be highlighted to the PMG.

ADTC Decision:

Routinely available in line with national guidance

Local restrictions on use:

Restricted to specialist initiation for the treatment of symptomatic chronic heart failure with reduced ejection fraction in adult patients.

Dupilumab

SMC2317

Dupixent® sub-cut injection

Indication:

In adults and adolescents 12 years and older as add-on maintenance treatment for severe asthma with type 2 inflammation characterised by raised blood eosinophils and/or raised fraction of exhaled nitric oxide (FeNO), who are inadequately controlled with high dose inhaled corticosteroids (ICS) plus another medicinal product for maintenance treatment.

ADTC Discussion points

ADTC noted that the restricted positioning would mean that this would only likely be used in a small number of patients. Expectation is that this medicine will be added to existing local guidance.

ADTC Decision:

Routinely available in line with national guidance

Local restrictions on use:

Restricted to specialist use for patients with severe asthma with type 2 inflammation and blood eosinophils ≥150 cells/microlitre and FeNO ≥25 parts per billion, and ≥4 exacerbations in the preceding year, who have previously received biologic treatment with anti-IgE or anti-IL-5 therapies.

Fostamatinib

SMC2300

Tavlesse® tablets

Indication:

Treatment of chronic immune thrombocytopenia (ITP) in adult patients who are refractory to other treatments

ADTC Discussion points

ADTC noted that most patients will usually respond to existing treatment options, therefore small patient numbers are anticipated.

ADTC Decision:

Routinely available in line with national guidance

Local restrictions on use:

Restricted to specialist use for the treatment of chronic immune thrombocytopenia (ITP) in adult patients who are refractory to other treatments

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Galcanezumab

SMC23213

Emgality® sub-cut injection

Indication:

Prophylaxis of migraine in adults who have at least 4 migraine days per month.

ADTC Discussion points

ADTC note that this will be incorporated into existing guidelines in due course.

ADTC Decision:

Routinely available in line with national guidance

Local restrictions on use:

Restricted to specialist use for the treatment of patients with chronic and episodic migraine who have had prior failure on three or more migraine preventive treatments.

Ozanimod

SMC2309

Zeposia® capsules

Indication:

Treatment of adult patients with relapsing remitting multiple sclerosis (RRMS) with active disease as defined by clinical or imaging features.

ADTC Discussion points

It was noted that this medicine would be expected to be incorporated into the existing RRMS guidance in due couse.

ADTC Decision:

Routinely available in line with national guidance

Local restrictions on use:

Treatment of adult patients with relapsing remitting multiple sclerosis (RRMS) with active disease as defined by clinical or imaging features is restricted to specialist use in patients suitable for, or requesting an oral treatment.

Ravulizumab

SMC2305

Ultomiris® infusion

Indication:

Treatment of adult patients with paroxysmal nocturnal haemoglobinuria (PNH):
- In patients with haemolysis with clinical symptom(s) indicative of high disease activity
- In patients who are clinically stable after having been treated with eculizumab for at least the past 6 months.

ADTC Discussion points

ADTC are still awaiting comment from local and national service prescribers. It was considered preferable to await this before making a final decision relating to formulary status.

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:

30/06/2021

Local restrictions on use:

Secukinumab

SMC2308

Cosentyx® pre-filled pen/ syringe

Indication:

Treatment of active non-radiographic axial spondyloarthritis with objective signs of inflammation as indicated by elevated C-reactive protein and/or magnetic resonance imaging evidence in adults who have responded inadequately to non steroidal anti inflammatory drugs.

ADTC Discussion points

This was the first licensed IL-17A inhibitor for this indication and was considered to be a useful addition to Formulary in light of the different mechanism of action.

ADTC Decision:

Routinely available in line with national guidance

Local restrictions on use:

Restricted to specialist use in accordance with local guidelines.

Upadacitinib

SMC2315

Rinvoq® MR tablets

Indication:

Treatment of moderate to severe active rheumatoid arthritis (RA) in adult patients who have responded inadequately to, or who are intolerant to one or more disease-modifying anti-rheumatic drugs (DMARDs). Upadacitinib may be used as monotherapy or in combination with methotrexate.

ADTC Discussion points

ADTC noted that this medicine submitted to SMC for use in moderate disease, but was restricted to severe disease only. Use in moderate disease therefore remains non-formulary

ADTC Decision:

Routinely available in line with national guidance

Local restrictions on use:

Restricted to specialist use in accordance with local guidelines for patients with severe disease (a disease activity score [DAS28] greater than 5.1) that has not responded to intensive therapy with a combination of conventional DMARDs and in patients with severe disease inadequately controlled by a TNF antagonist in whom rituximab is not appropriate.

Beclomethasone/ Formoterol/ Glycopyrronium

SMC2335

Trimbow® inhaler

Indication:

Maintenance treatment of asthma, in adults not adequately controlled with a maintenance combination of a long-acting beta2-agonist and medium dose of inhaled corticosteroid, and who experienced one or more asthma exacerbations in the previous year.

ADTC Discussion points

Support from MCN prescribing subgroup to add to Formulary. This triple inhaler is already Formulary for use in patients with COPD and this is a new indication for asthma.

ADTC Decision:

Routinely available in line with national guidance

Local restrictions on use:

Buprenorphine with Naloxone

SMC2316

Suboxone® sublingual film

Indication:

Substitution treatment for opioid drug dependence, within a framework of medical, social and psychological treatment. The intention of the naloxone component is to deter intravenous misuse. Buprenorphine/naloxone is indicated in adults and adolescents over 15 years of age who have agreed to be treated for addiction.

ADTC Discussion points

Within NHSGGC, Espranor remains the preferred choice when buprenorphine is required. Clinicans do not see a need to add this new formulation to Formulary at this time as suitable alternatives are available.

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:

Doravirine

SMC2332

Pifeltro® tablets

Indication:

In combination with other antiretroviral medicinal products, for the treatment of adults infected with HIV-1 without past or present evidence of resistance to the non-nucleoside reverse transcriptase inhibitor (NNRTI) class.

ADTC Discussion points

This medicine may be a useful alternative treatment option for a small number of patients.

ADTC Decision:

Routinely available in line with national guidance

Local restrictions on use:

Restricted to use by HIV specialists

Doravirine/Lamivudine/Tenofovir

SMC2333

Delstrigo® tablet

Indication:

Treatment of adults infected with HIV-1 without past or present evidence of resistance to the non-nucleoside reverse transcriptase inhibitor (NNRTI) class, lamivudine, or tenofovir.

ADTC Discussion points

This combination may be a useful alternative for a small number of patients.

ADTC Decision:

Routinely available in line with national guidance

Local restrictions on use:

Restricted to use by HIV specialist

Formoterol/ Glycopyrronium/ Budesonide

SMC2321

Trixeo® Aeros pressurised inhalation

Indication:

Maintenance treatment in adult patients with moderate to severe chronic obstructive pulmonary disease (COPD) who are not adequately treated by a combination of an inhaled corticosteroid and a long-acting beta2-agonist or combination of a long-acting beta2-agonist and a long-acting muscarinic antagonist.

ADTC Discussion points

This is the 2nd triple inhaler for COPD. Support from MCN prescribing subgroup to add to Formulary

ADTC Decision:

Routinely available in line with national guidance

Local restrictions on use:

Restricted to use in patients with severe COPD (forced expiratory volume in one second [FEV1] less than 50% predicted normal).

Acalabrutinib

SMC2346

Calquence® capsules

Indication:

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

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 as monotherapy for the treatment of adult patients with previously untreated CLL who have a 17p deletion or TP53 mutation and in whom chemo-immunotherapy is unsuitable.

Acalabrutinib

SMC2348

Calquence® capsule

Indication:

Monotherapy for the treatment of adult patients with chronic lymphocytic leukaemia (CLL) who have received at least one prior therapy.

ADTC Discussion points

This will be referred to WoSPASG for 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 for patients with relapsed/refractory CLL who have had at least one previous therapy, in whom chemo-immunotherapy is unsuitable

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Brentuximab

SMC2310

Adcetris® infusion

Indication:

In combination with cyclophosphamide, doxorubicin and prednisone (CHP) for adult patients with previously untreated systemic anaplastic large cell lymphoma (sALCL).

ADTC Discussion points

This will be referred to WoSPASG for 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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Brigatinib

SMC2314

Alunbrig® tablets

Indication:

As monotherapy for the treatment of adult patients with anaplastic lymphoma kinase (ALK)-positive advanced non-small cell lung cancer (NSCLC) previously not treated with an ALK inhibitor.

ADTC Discussion points

This will be referred to WoSPASG for 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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Daratumumab

SMC2302

Darzalex® infusion

Indication:

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.

ADTC Discussion points

This will be referred to WoSPASG for 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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Daratumumab

SMC2326

Darzalex® injection

Indication:

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

ADTC Discussion points

This will be referred to WoSPASG for 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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Entrectinib

SMC2295

Rozlytrek® capsules

Indication:

Monotherapy for the treatment of adult and paediatric patients 12 years of age and older with solid tumours expressing a neurotrophic tyrosine receptor kinase (NTRK) gene fusion,
- who have a disease that is locally advanced, metastatic or where surgical resection is likely to result in severe morbidity, and
- who have not received a prior NTRK inhibitor
- who have no satisfactory treatment options

ADTC Discussion points

This will be referred to WoSPASG for protocol development. Capacity for genetic testing of this mutation will be required to be increased, hence the need for implementation plans.

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:

31/08/2021

Local restrictions on use:

Entrectinib

SMC2294

Rozlytrek® capsules

Indication:

Monotherapy for the treatment of adult patients with ROS1-positive, advanced non-small cell lung cancer (NSCLC) not previously treated with ROS1 inhibitors.

ADTC Discussion points

This will be referred to WoSPASG for 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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Isatuximab

SMC2303

Sarclisa® infusion

Indication:

In combination with pomalidomide and dexamethasone, for the treatment of adult patients with relapsed and refractory multiple myeloma (RRMM) who have received at least two prior therapies including lenalidomide and a proteasome inhibitor (PI) and have demonstrated disease progression on the last therapy.

ADTC Discussion points

This will be referred to WoSPASG for 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 for use in combination with pomalidomide and dexamethasone for patients receiving fourth-line therapy (with prior therapies including lenalidomide and a proteasome inhibitor) and have demonstrated disease progression on the last therapy.

Leuprorelin acetate

SMC2320

Prostap® 3 D pre-filled syringe

Indication:

Treatment in pre- and perimenopausal women with advanced breast cancer suitable for hormonal manipulation

ADTC Discussion points

This will be referred to WoSPASG for protocol development

ADTC Decision:

Routinely available in line with local or regional guidance

Local restrictions on use:

Use in the treatment in pre- and perimenopausal women with advanced breast cancer suitable for hormonal manipulation is restricted to specialist initiation in accordance with regional protocol.

Leuprorelin acetate

SMC2319

Prostap® SR pre-filled syringe

Indication:

as adjuvant treatment in combination with tamoxifen or an aromatase inhibitor, of endocrine responsive early stage breast cancer in pre- and perimenopausal women at higher risk of disease recurrence (young age, high grade tumour, lymph node involvement). In women who have received chemotherapy, premenopausal status must be confirmed after completion of chemotherapy.

ADTC Discussion points

This will be referred to WoSPASG for protocol development

ADTC Decision:

Routinely available in line with local or regional guidance

Local restrictions on use:

Use as adjuvant treatment in combination with tamoxifen or an aromatase inhibitor, of endocrine responsive early stage breast cancer in pre- and perimenopausal women at higher risk of disease recurrence is restricted to specialist initiation in accordance with regional protocol.

Trametinib

SMC2328

Mekinist® tablet

Indication:

In combination with dabrafenib for the treatment of adult patients with unresectable or metastatic melanoma with a BRAF V600 mutation.

ADTC Discussion points

This will be referred to WoSPASG for 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 for use after first-line therapy

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Alpelisib

SMC2339

Piqray® tablets

Indication:

In combination with fulvestrant for the treatment of postmenopausal women, and men, with hormone receptor (HR)-positive, human epidermal growth factor receptor 2 (HER2)-negative, locally advanced or metastatic breast cancer with a PIK3CA mutation after disease progression following endocrine therapy as monotherapy.

ADTC Discussion points

ADTC Decision:

Not routinely available as not recommended for use in NHSScotland

Local restrictions on use:

Apalutamide

SMC2323

Erleada® tablets

Indication:

In adult men for the treatment of metastatic hormone-sensitive prostate cancer (mHSPC) in combination with androgen deprivation therapy.

ADTC Discussion points

ADTC Decision:

Not routinely available as not recommended for use in NHSScotland

Local restrictions on use:

Apremilast

SMC2340

Otezla® tablets

Indication:

Treatment of adult patients with oral ulcers associated with Behçet's disease who are candidates for systemic therapy

ADTC Discussion points

ADTC Decision:

Not routinely available as not recommended for use in NHSScotland

Local restrictions on use:

Dupilumab

SMC2324

Dupixent® pre-filled pen/ syringe

Indication:

As an add-on therapy with intranasal corticosteroids for the treatment of adults with severe chronic rhinosinusitis with nasal polyposis for whom therapy with systemic corticosteroids and/or surgery do not provide adequate disease control

ADTC Discussion points

ADTC Decision:

Not routinely available as not recommended for use in NHSScotland

Local restrictions on use:

Gasdegib

SMC2341

Daurismo® tablets

Indication:

In combination with low-dose cytarabine, for the treatment of newly diagnosed de novo or secondary acute myeloid leukaemia (AML) in adult patients who are not candidates for standard induction chemotherapy.

ADTC Discussion points

ADTC Decision:

Not routinely available as not recommended for use in NHSScotland

Local restrictions on use:

Imipenem/ Cilastatin/ Relabactam

SMC2342

Recarbrio® infusion

Indication:

Treatment of:
- hospital-acquired pneumonia (HAP), including ventilator associated pneumonia (VAP), in adults.
- bacteraemia that occurs in association with, or is suspected to be associated with HAP or VAP, in adults.

ADTC Discussion points

ADTC Decision:

Not routinely available as not recommended for use in NHSScotland

Local restrictions on use:

Mercaptamine

SMC2343

Cystadrops® eye drops

Indication:

Treatment of corneal cystine crystal deposits in adults and children from 2 years of age with cystinosis.

ADTC Discussion points

ADTC Decision:

Not routinely available as not recommended for use in NHSScotland

Local restrictions on use:

Omalizumab

SMC2344

Xolair® pre-filled syringe, injection

Indication:

As add-on therapy with intranasal corticosteroids (INC) for the treatment of adults (18 years and above) with severe chronic rhinosinusitis with nasal polyps for whom therapy with INC does not provide adequate disease control.

ADTC Discussion points

ADTC Decision:

Not routinely available as not recommended for use in NHSScotland

Local restrictions on use:

Talazoparib

SMC2325

Talzenna® capsules

Indication:

As 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 been previously treated with an anthracycline and/or a taxane in the (neo) adjuvant, locally advanced or metastatic setting unless patients were not suitable for these treatments.
Patients with hormone receptor (HR)-positive breast cancer should have been treated with a prior endocrine-based therapy, or be considered unsuitable for endocrine-based therapy.

ADTC Discussion points

ADTC Decision:

Not routinely available as not recommended for use in NHSScotland

Local restrictions on use:

Cannabidiol

SMC2263

Epidyolex® oral solution

Indication:

For use as adjunctive therapy of seizures associated with Lennox-Gastaut syndrome, in conjunction with clobazam, for patients 2 years of age and older.

ADTC Discussion points

The adult protocol for use was approved and introduced in March, at which point to align with policy, ADTC Executive allowed addition to Formulary following the postponement of the previous ADTC meeting.

ADTC Decision:

Routinely available in line with local or regional guidance

30/04/2021

Local restrictions on use:

Restricted to specialist use in combination with clobazam for the adjunctive therapy of seizures associated with Dravet syndrome and Lennox-Gastaut syndrome in accordance with local protocol (requires access to StaffNet).

Afamelanotide

1251/17

Scenesse® implant

Indication:

Prevention of phototoxicity in adult patients with erythropoietic protoporphyria (EPP).

ADTC Discussion points

Accessible via the UO pathway with cases requring to be registered. Formulary status is expected to be reconsidered following reassessment by SMC.

ADTC Decision:

Routinely available in line with national guidance

Local restrictions on use:

Restricted to specialist use for the prevention of phototoxicity in adult patients with erythropoietic protoporphyria (EPP).
Formulary status will be reconsidered following the reassessment by SMC (expected 2024).