NHS
Derby and Derbyshire
Integrated Care Board

JOINT AREA PRESCRIBING COMMITTEE (JAPC) DECISION AND JUSTIFICATION LOG

Meeting Date: 10th December 2024 **Updated by:** Policy Team

Ethical Framework

Chair to ensure that all decisions made are in line with the ICBs Ethical Framework, following examples of evidence of clinical and cost effectiveness, health care need and capacity to benefit, policy driver/strategic fit.

Declarations of Interest

Committee members are reminded of their obligation to declare any interest they may have on any issues arising at committee meetings which might conflict with the business of the ICB.
Declarations declared by members of the JAPC are listed in the Register of Interests and included with the meeting papers. The ICB's Registers of Interests are also available via the ICB's Corporate Governance Manager.

Agenda Item number	Agenda Item Title	Owner	Summary of Discussion	Decision & Justification	Action(s)
	Confirmation of Quoracy	Chair	Quoracy established at 13:38		
	Declarations of Interest for today's meeting	Chair	None		
1	Apologies	Chair	Will Elston, Steve Hulme, Kate Needham, Alison Brailey		
2	Conflict of interest declarations a. Register of interests	Chair	None declared. Chair reminded members of the importance of declaring any interests		
3	Declarations of any other business	Chair	None declared		
4	JAPC Action Summary	Emily Khatib	Discussed. - OPAT – To bring back to JAPC in January - Liothyronine, JAPC ToR and HCD for further discussion as per agenda		

5	JAPC Decision & Justification Log Nov 2024	Emily Khatib	For ratification	Ratified	To publish on website
6	Matters arising a. Annual Horizon Scan 2025/26 DRAFT	All	The annual horizon scan was presented to JAPC members which is taken from the SPS produced Prescribing Outlook for 2025-26 and uses Derbyshire population figures to estimate the cost or savings impact of new medicines, NICE recommendations, biosimilars and patent expiries in the next financial year. Most notable expenses expected include tirzepatide and semaglutide for weight loss, new high cost drug treatments for Alzheimer's disease.	Noted	
	b. JAPC ToR 2023/24 DRAFT		Post restructure review of the Terms of Reference. Minor amendments made as per comments from JAPC members in November meeting. Final amended version to be circulated by email.	For email agreement	Circulate to members
	c. Acute Management of Potential Adverse Treatment Effects of Lecanemab		Although not currently available in the NHS, Eisai (the manufacturer and market authorisation holder for lecanemab (Leqembi®)) has begun to make the drug available for patients to access through independent sector clinics. This document provides a short briefing for clinicians who may subsequently be asked to support referrals for private treatment or otherwise assess, advise and possibly treat a small number of patients who could present with potential adverse treatment effects, including symptomatic Amyloid-Related Imaging Abnormalities (ARIA).	Noted	No action
7	JAPC Bulletin DRAFT November 2024	All	For ratification	Ratified	Publish on website
8	New Drug Assessment /Traffic Light Addition a. Ogluo	Emily Khatib	Ogluo is a new form of glucagon which is significantly more expensive than our standard current treatment	Agree to classify Ogluo **DNP** and GlucaGen Hypokit **GREEN**	Update on website

			(GlucaGen Hypokit). If prescribing were permitted it would be a significant cost pressure. Ogluo is a pre-filled, single-dose pen for subcutaneous administration. GlucaGen is a glass vial which requires reconstitution and can be administered SC/IM/IV. Ogluo has a shelf-life of 30 months stored at room temperature (not exceeding 25°C). GlucaGen has a shelf-life of 36 months if stored in a refrigerator, or 18 months stored at room temperature (not exceeding 25°C). It is non-formulary on the Nottingham APC website, Sheffield Children's Hospital formulary has it as Restricted with no further details. Local specialist clinicians are in agreement to classify Ogluo **DNP** and GlucaGen Hypokit **GREEN**.		
9	**Clinical Guidelines** a. Stoma	Emily Khatib	The stoma guidance has undergone comprehensive review in close collaboration with specialist stoma care nurses (SCNs). The previous accessory guideline focused solely on cost, causing reported issues such as nurse unfamiliarity and unfavourable experience with certain recommended products. The final draft guidance incorporates expert SCN knowledge, feedback from trial of unfamiliar products, and product testing of MARs and MAR wipes and barrier sprays and wipes.	Guidance approved	Publish on website
10	**PGDs** a. MPOX Vaccine	Emily Khatib	This PGD is published on the East Midlands Screening and Immunisations Team (SIT) website and is authorised for use across the East Midlands.	Noted	No action

			The UK Health Security Agency (UKHSA) has developed this PGD to facilitate the delivery of publicly funded immunisation in England in line with national recommendations. This PGD is for the administration of the non-replicating, live modified vaccinia virus Ankara - Bavarian Nordic (MVA-BN), to individuals identified for immunisation in response to preventing the spread of monkeypox virus (MPXV).		
11	**Shared Care** a. Riluzole	Emily Khatib	Riluzole SCA reviewed in light of cost changes and licensing differences between riluzole preparations. Riluzole is **AMBER** for treatment of the Amyotrophic Lateral Sclerosis (ALS) form of Motor Neurone Disease (MND) (adult services) and this shared care agreement supports its use. The existing SCA states the film coated tablets should be used because they are the most cost-effective option, and these should be crushed to administer down feeding tubes and for those with swallowing difficulties. Now, the tablets are significantly more expensive that the oral suspension and orodispersible films. Only the oral suspension is licensed to be given down enteral feeding tubes. The film coated tablets are listed as 2nd line option in NEWT for patients with enteral tubes. Specialists advise that the orodispersible films are not suitable for all patients as many struggle to open the packaging and they leave a numb feeling in the mouth. The SCA has been updated to reflect the new recommendation that patients with swallowing difficulties use orodispersible preparation and patients requiring administration down an enteral tube, use the oral suspension.	Changes approved.	Publish on website

	b. Somatropin and Somatrogon		Somatropin is shared care for several indications in children and adults. Somatrogon is a newer agent licensed only for the use of growth hormone deficiency in children and adolescents and is a weekly injection, instead of daily. Additional monitoring requirements for somatrogon will be undertaken by the specialist. It is expected that 2 patients per year will require somatrogon, the cost of somatrogon is comparable to somatotrophin and will be used in patients who otherwise would have somatotrophin. Somatrogon NICE TA863: If people with the condition and their clinicians consider somatrogon to be 1 of a range of suitable treatments (including any preparation of somatropin) discuss the advantages and disadvantages of the available treatments. After that discussion, if more than 1 treatment is suitable, choose the least expensive. Take account of administration costs, dosage, price per dose and commercial arrangements. The recommendation is to re-classify somatrogon from **RED** to **AMBER** and for the revised SCA to be approved.	Agree to re-classify Somatrogon from **RED** to **AMBER**. SCA agreed with minor amendments.	Update on website. Action minor amendments and publish on website.
12	**Miscellaneous** a. HCD algorithm – Macular oedema due to BRVO or CRVO	Emily Khatib	Faricimab (anti-VEGF) is recommended as an option for treating visual impairment caused by macular oedema after central or branch retinal vein occlusion in adults - only if the company provides faricimab according to the commercial arrangement. Macular oedema after retinal vein occlusion is usually treated first with aflibercept or ranibizumab, which are already recommended by NICE. Faricimab is another treatment option that works in a similar way.	Algorithm approved	Publish on website

			Evidence from clinical trials shows that faricimab is likely to work as well as aflibercept for people who have not had an anti-VEGF treatment. There is limited evidence for how well faricimab works for people who have had an anti-VEGF treatment. But clinical experts agreed that faricimab is likely to work as well as aflibercept for people who have had an anti-VEGF treatment. There are no direct or indirect comparisons of faricimab with ranibizumab. A cost comparison suggests faricimab has similar costs and overall health benefits to aflibercept. So faricimab is recommended as an additional treatment option if it is used in the same population. Comparison of costs to ranibizumab & alflibercept is difficult due to the individualised treat & extend regime, treatment intervals depend on a patient's response after the initial three-monthly doses. PAS costs for faricimab and aflibercept (Eylea) are currently the same however an aflibercept biosimilar is expected in 2025, the patent expiry of Eylea is May 25. This would make aflibercept a more cost-effective option so faricimab has been put on the algorithm below aflibercept. The PAS cost of ranibizumab biosimilar is currently approximately 50% of the PAS cost of aflibercept (Eylea) and faricimab. The recommendation is for JAPC to adopt the updated algorithm for macular oedema due to BRVO/CRVO.		
	b. Specialised Circulars	Emily Khatib	Final draft guidance is no longer being actioned. Action will be taken once product TAs launched. No actions this month.	Acknowledged	

13	Subgroups of JAPC a. Guideline Group Key Messages	Alex Statham	Chapter 13 (Skin) updated as per annual process. Alterations include, MHRA warning for Epimax ointment & Epimax paraffin-free ointment added with link to MHRA alert. Brand names of corticosteroids removed to encourage generic prescribing. Additional wording added to cortisteroid section to aid prescribing -"Water-miscible corticosteroid creams are suitable for moist or weeping lesions, whereas ointments are generally chosen for dry, lichenfied or scaly lesions or where a more occlusive effect is required ". Clarification of NICE recommendations for the use of topical antifungals and updated to reflect changes in guidance. Inclusion of reference to yellow card scheme regarding topical steroids. Clarification of antibiotic use alongside topical steroids to bring in line with NICE recommendations. Clarification of licenses for pimecrolimus & tacrolimus ointment. Removed benzoyl peroxide 4% cream due to discontinuation. Inclusion of MHRA warning for topical retinoids & oral tetracyclines being contraindicated during pregnancy. Information on oral preparations for acne added to bring in line with NICE guidance - "Antibiotic monotherapy is poor management and will only partially treat the acne process. In order to minimise the development of antibiotic resistance always use a topical (non-antibiotic) agent alongside oral antibiotic. Even intermittent treatment can help prevent antibiotic resistance developing." References to Changing Faces and link to website added in camouflagers section. Changing Faces is a charity which patients living with scars can be referred to for skin camouflage and a range of emotional support services.	Agreed	

			Inclusion of ivermectin with indications, traffic light classification and dosage aid. Inclusion of ivermectin cutaneous cream in rosacea section as TLC as green. Ingenol mebutate removed due to discontinuation. Existing hyperlinks updated and links to JUCD & NICE CKS added and drug classifications specified where missing. Other minor updates to clinical guidelines and website including: Prescribing Advice for Hyperprolactinaemia updated with MHRA alert regarding essential monitoring of blood pressure for patients prescribed bromocriptine. Infant feeding guideline re-named as Non-Hypoallergenic Specialist Infant Products guideline. Reference to soya products and galactosaemia removed due to discontinuation of all soya products. Specials & Expensive Liquids Guideline amendments include updates to diazepam, pregabalin, riluzole to bring in line with NEWT guidance and clarify switching formulations and increased epilepsy risk with pregabalin. Chloral Hydrate Position Statement reviewed with no changes. Dementia in Primary Care guideline reviewed with minor amendments - contact details and prices updated. High strength rivastigmine patch added. Bloods for assessment changed to reflect OA CMHT referral requirements. Due to product discontinuation, all references to Kay-Cee-L (potassium) syrup removed from Chapter 9 Nutrition & Blood, Specials & Expensive Liquids guideline and potassium traffic light page. Reference to Salazopyrin brand removed from Sulfasalazine SCA.		

	b. High Cost Drugs Working Group Minutes Oct 24	Emily Khatib	Noted		
FOR INFORMATION AND REPORT BY EXCEPTION					
14	MHRA Drug Safety Update Nov  14. Drug_Safety_Update_	Chair	Noted		
15	Horizon Scan a. Monthly Horizon Scan October		Each month SPS published its new drugs monthly newsletter. This agenda item is for JAPC to acknowledge new drug launches and to agree or comment upon the suggested actions. **TLC amendments:** Elafibranor (*Iqirvo*) 80mg tablet Classify as **RED** as per NHSE commissioning intentions. Fruquintinib (*Fruzaqla*)1mg and 5mg capsules Classify **RED** as per NHSE commissioning intentions.	Traffic light classifications agreed	Update on website
16	NICE Template – November 2024		Classify as per below in line with NICE TAs: **TA1012:** Avapritinib for treating advanced systemic mastocytosis. Classify **RED** **TA1014:** Alectinib for adjuvant treatment of ALK-positive non-small-cell lung cancer. Classify **RED**	All agreed	Update on website

			TA1015: Teclistamab for treating relapsed and refractory multiple myeloma after 3 or more treatments. Classify **RED** **TA1016:** Elafibranor for previously treated primary biliary cholangitis. Classify **RED** **TA1017:** Pembrolizumab with chemotherapy before surgery (neoadjuvant) then alone after surgery (adjuvant) for treating resectable non-small-cell lung cancer. Classify **RED** **TA1018:** Fedratinib for treating disease-related splenomegaly or symptoms in myelofibrosis. Classify **RED** **TA1019:** Crovalimab for treating paroxysmal nocturnal haemoglobinuria in people 12 years and over. Classify **RED** **TA1020:** Eplontersen for treating hereditary transthyretin-related amyloidosis. Classify **RED**		
17	MORAG		No update this month		
18	Minutes of other prescribing committees a. Final October 2024 Minutes DCHS Chesterfield b. Stoke & Staffs IMOG minutes October 2024 c. UHDB October approved DTC minutes		Noted		

	d. Tameside & Glossop ICB IMOG Minutes October 2024 e. South Yorkshire ICB DRAFT APG Minutes October 2024				
19	Traffic Lights a. Liothyronine	Steve Jones	Liothyronine for treatment resistant depression is currently **RED** status. Treatment Resistant Depression is an unlicensed indication for liothyronine (T3) supported by a number of open studies and reviews and is included as an augmentation option in the current NICE guidelines for the treatment of depression. Current antidepressants in unipolar depression, for adults aged 18 and over JAPC guidance recommends liothyronine as step 4 option for treatment resistant depression for specialist initiation only. Where liothyronine is prescribed for the treatment of depression only, this should be under the advice of an NHS consultant psychiatrist. Where liothyronine is prescribed for the treatment of depression in patients with suspected or established thyroid disease, this should be under the advice of and NHS consultant psychiatrist and NHS consultant endocrinologist. Liothyronine has a clinical role to play in the management of treatment depression and is suitable for prescribing and monitoring in primary care when initiation has been undertaken by specialist mental health services. Request for liothyronine for treatment resistant depression to be re-classified as **GREY** – suitable for	Agree to classify as **GREY** specialist initiation Agree that written communication from DHcFT to GPs will include direct contact details for DHcFT specialist mental health pharmacists to support with GP queries	Update website

			prescribing in primary care following initiation by specialist mental health services.		
	b. Varenicline	Emily Khatib	Varenicline (Champix) was previously available until 2021 when distribution was stopped by the MHRA due to unacceptable limits of nitrosamines in varenicline products which initiated a class 2 medicines recall of all in-date batches of Champix®. When this occurred, the TLC was changed from GREEN to DNP and Champix brand has been commercially unavailable since then. A generic version of varenicline has now been approved and stocks are becoming available from wholesalers. It is not yet listed in the Drug Tariff (Nov 2024) or MIMS. Generic varenicline is on the GP clinical systems, there has been an unlicensed product available imported from Canada. Currently our providers of smoking cessation support do not wish to pursue a PGD for these, however a template for varenicline has been produced by SPS, and one for cytisinicline is currently in progress. Derby and Derbyshire Public Health Stop Smoking services want to be able to prescribe or ask GPs to prescribe generic varenicline now it is coming back into stock. Since 2021 cytisinicline has become available for prescribing for patients referred to stop smoking service. The recommendation is to change the TLC for varenicline from **DNP** to **GREEN** with caveat the same as for cytisinicline: Patients should be referred to stop smoking services to discuss support options for	Agree to classify **GREEN**	Update on website

			smoking cessation. GP may prescribe following stop smoking service request.		
20	AOB	Emily Khatib	Continence guidelines. Updated guidance not yet published on website due to concerns with Appendix 1, specifically around the practicalities of prescribing prophylactic IM gentamicin. For further discussion with DCHS/continence team	Agree to temporarily remove appendix 1 and publish guidance	Publish on website

Date of Next meeting: Tuesday 14th January 2025