Therapeutics Advisory Group

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Norfolk and Waveney Integrated Care System

Norfolk & Waveney Horizon Scanning (HS) Summary for Therapeutics Advisory Group (TAG) and Norfolk and Waveney D&T Committee – April 2025

Summary of Horizon Scanning Treatments likely to impact in 24-25. *For detail see Appendix 1*

Specialist Pharmacy Service (SPS) produces a range of information to support managed entry of new drugs into the NHS, to assist organisations in developing medicines management policies and to inform prescribing decisions when a product has been launched. Highlights of their Prescribing Outlook with suggested TAG action is noted below.

How is content of the New Medicines section of the SPS website decided?

The SPS Service continually scans data sources to identify new drugs/licence changes/formulations, etc. in development, with a focus on those that will have implications for the NHS. SPS Prescribing Outlook provides information and intelligence on medicines in development with predicted launches due over the next 3 years and focuses on medicines with potential for significant clinical or financial impact in the NHS.

There are over 1,000 new medicines pages on the SPS website. Monographs containing brief details such as name, company, stage of development, pharmacology and epidemiology are created if the new medicine:

- is likely to reach the UK market, and
- is in a phase 3 clinical trial or is being fast tracked, and
- is new or has a potential major licence change or a is being developed in a new formulation.

Figures do not include administration or monitoring costs.

ICB Commissioned treatments – 71 Identified through Horizon scanning	
NICE TA published	10
NICE TA in development	19
No NICE in development / expected	12
Terminated appraisal / in trial phase	30

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List below is treatments of highest identified financial Risk

Highest Risks – Mitigation is Trusts using in appropriate place in pathways			
NICE TA status	Notes	Financial assumptions	Potential annual Risk
Lecanemab (Alzheimers)	Initially - NICE TA - not recommended. Result of comments and discussion due March 2025	Assuming lecanemab costs £9,450/year and lecanemab is offered to 20% of those NICE estimates are eligible (14,000 adults or 24.5 per 100,000 people)	£1.6 - £3.2M
Donanemab (Alzheimers)	Initially - NICE TA - not recommended. Result of comments and discussion due March 2025	Cost of 1 year of treatment would be £11,450. Costs if Donanemab is used instead of Lecanemab are difficult to predict.	£2M
Tirzepatide (Weight management)	TA launched Dec 2024 and awaiting the NHSE variation in implementation publication - expected late January. Available to tier 3 within 90 days. Additional offer to be within 180 days.	Annual cost/ patient based on a maximum maintenance dose of 15mg once weekly is £1,586.	£44M
Ritlecitinib (Alopecia)	Considered at TAG and afforded a RED classification. Use and monitoring to be in line with the NICE TA. All prior pathway choices to have been tried as per NICE. Not implemented fully yet. PAS available	NICE estimates uptake amongst adults and adolescents with severe alopecia areata will be 22.5% in year 1 (3,065 people, or 5.4 per 100,000 people). PAS price, the cost impact will be less.	£605k - £1.3M
Bevacizumab (Wet AMD)	Been to TAG and afforded a Red classification - this is an additional 2nd line option for use in Wet AMD. To be added to NHSE framework in April 2025. PAS available.	Assuming Lytenava is priced at £200/vial and that it is administered 4-6 weekly (average 10 doses/year), annual cost would be £2,000.	£50k
Budesonide (Glomerular disease)	Been to TAG and afforded Red classification. The aim of this treatment is to prevent or delay kidney failure and associated complications.	NICE expects the resource impact of implementing its recommendations will be less than £8,800 per 100,000 people	£56k
Fezolinetant (Menopause)	Selected for NICE development - no date of expected NICE TA draft	Annual cost of fezolinetant is £582. Assuming it is offered to 5% of women with severe symptoms	£42 - £294K

Relugolix/estradiol/ norethisterone	Relugolix–estradiol–norethisterone (relugolix combination therapy [CT]) is not recommended – Awaiting final NICE.	Ryeqo costs ~£940 per patient/year; (Endometriosis)	£180k
Linzagolix (Endometriosis)	NICE in scope - expected publication June 2025. Likely same outcome as above.	Linzagolix 100mg/day and 200mg/day costs £1,040 per patient/year	£200k
Semaglutide (CVD risk reduction)	In development - NO NICE confirmed yet.	Wegovy costs £1,926 in year 1 and £2,285 in second and subsequent years. Assume use in 3% of population	£2.3M
Dupilumab (COPD)	Selected for NICE development – in scope only at present	Annual cost of dupilumab is £16,444 per patient/year (list price, 300mg 2-weekly; PAS available for other indications)	£220k
Ruxolitinib	No NICE yet – awaiting in development date	A 60g tube of Opzelura costs £657 and average use is estimated at 10 tubes/year. Annual price per patient/year £	£240k

NEW - Spontaneous Urticaria, Prurigo Nodularis, Geographic atrophy treatments in the pipeline – In Trial phase at present but likely high-cost pressure.

NOTE – all other horizon scanning treatments offer cost neutral or small saving as they are additional options to already established treatments within pathway.

Biosimilar Opportunities

Opportunities – Use in appropriate place in pathways			
Drug	Annual spend 23_24	Approximate saving (50% reduction & 100% switch)	Notes
Ustekinumab – biosimilar	£3.2M	£1.6M	Available - Good uptake so far
Omalizumab	£141k	£70k	Expected Q1 2025 – 4 additional biosimilars in development
Aflibercept	£4.6M	£2.3M	Expected Q4 2025 – 8 possible but only 2mg option expected
Golimumab	£724k	£360k	Expected Q4 2025 – ONE biosimilar being assessed
Vedolizumab	£1.76M	£800k	Expected Q2 2026 – No submissions yet
Other patent expiries of note for 2025 which may lead to generic/ biosimilar cost saving opportunities	Ticagrelor - June 2025, Eltrombopag - September 2025, Denosumab – November 2025,		

Patent Expiries - 2024

Drug	***BNF***	***Commissioner***	***Loss of exclusivity year***	***Loss of exclusivity month***	***Notes***	***Generic/ biosimilar available or in development***
Ustekinumab	1	ICB (adults) NHSE (delegated, children)	2024	July	Crohn's disease. Manufacturers have indicated they do not intend launching some ustekinumab presentations until 2025. See the Biosimilar tab or Biosimilars on SPS website.	Y
Ustekinumab	10	ICB	2024	July	Psoriatic arthritis. Manufacturers have indicated they do not intend launching some ustekinumab presentations until 2025. See the Biosimilar tab or Biosimilars on SPS website.	Y
Ustekinumab	13	ICB (adults) NHSE (delegated, children)	2024	July	Psoriasis. Manufacturers have indicated they do not intend launching some ustekinumab presentations until 2025. See the Biosimilar tab or Biosimilars on SPS website.	Y
Plerixafor	9	NHSE (retained)	2024	July/August		Y

Pomalidomide	8	NHSE (delegated)	2024	August	Loss of exclusivity based on market exclusivity date	Y
Romiplostim	9	ICB	2024	August		Y
Sucroferric oxyhydroxide	9	NHSE (delegated)	2024	August	Loss of exclusivity based on market exclusivity date. Generic products unlikely to enter market before 2028 as additional formulation-related patents apply.	
Aztreonam *(Cayston)*	5	NHSE (delegated)	2024	September	Inhalation formulation	
Bosutinib	8	NHSE (delegated)	2024	September		Y
Aripiprazole *(Abilify Maintena)*	4	ICB	2024	October	Depot injection has an active formulation patent until 18/10/2024	
Certolizumab pegol	10	ICB	2024	October	No timelines available on when biosimilars will become available	Y
Certolizumab pegol	13	ICB	2024	October	No timelines available on when biosimilars will become available	Y
Fluocinolone acetonide (*Iluvien*)	11	ICB	2024	October	Intraviteal implant	
Saxagliptin *(Onglyza)*	6	ICB	2024	October	Applies to saxagliptin monotherapy products	Y
Liraglutide	6	ICB	2024	November	Originator product (*Victoza*) will be discontinued for diabetes but biosimilars are in development	Y
Eribulin	8	NHSE (delegated)	2024	December		Y
Indacaterol (*Onbrez)*	3	ICB	2024	December	Applies to indacaterol monotherapy products	
Radium-223 dichloride	8	NHSE (delegated)	2024	December		

Patent Expiries – 2025

Drug	***BNF***	***Commissioner***	***Loss of exclusivity year***	***Loss of exclusivity month***	***Notes***	***Generic/ biosimilar available or in development***
Ustekinumab	1	ICB	2025	Q1	Patent relating to ulcerative colitis indication expires in 2039. Potential early access agreements may allow biosimilar ustekinumab products to be used for this indication earlier (in 2025), although ongoing legal challenges make this uncertain. See information on biosimilar ustekinumab on the SPS website.	Y

Dalbavancin	5	ICB (adults and children) NHSE (delegated, complex skin infections in children)	2025	February	Loss of exclusivity based on market exclusivity date, but may have an additional year of market exclusivity in the UK meaning generics would not launch until 2026	Y
Fluticasone/ formoterol *(Flutiform)*	3	ICB	2025	February	Fluticasone propionate / formoterol fumarate	Y
Canakinumab	8	NHSE (retained)	2025	April		
Golimumab	10	ICB (adults) NHSE (delegated, children)	2025	April		Y
Axitinib	8	NHSE (delegated)	2025	June		Y
Pertuzumab *(Perjeta)*	8	NHSE (delegated)	2025	June	Loss of exclusivity date could be later (2029) for some indications which are covered by additional patents	Y
Ticagrelor	2	ICB	2025	June	Film-coated tablets only. There is an ongoing legal case and a small probability that generic competition may be blocked until 2036.	Y
Aclidinium bromide *(Eklira Genuair)*	3	ICB	2025	July	Additional patent on dose may protect until 2029	
Lixisenatide (*Lyxumia*)	6	ICB	2025	July	Originator product (*Lyxumia*) was discontinued for diabetes and UK stock exhausted in December 2023	
Avanafil	7	ICB	2025	September		
Eltrombopag	9	ICB	2025	September	Loss of exclusivity date could be later (2028) for some indications which are covered by additional patents.	Y
Isavuconazonium sulfate	5	NHSE (delegated)	2025	October	Market exclusivity may be extended to October 2027	
Vandetanib	8	NHSE (delegated)	2025	October		
Aflibercept *(Eylea)*	11	ICB (adults) NHSE (delegated, infants)	2025	November	Loss of exclusivity date could be later for the 8mg/dose product (uncertain). Biosimilars already licensed are not indicated for retinopathy of prematurity.	Y
Denosumab	6	ICB	2025	November	Patent applies to both *Prolia* and *Xgeva* indications	Y
Pazopanib	8	NHSE (retained, soft tissue sarcoma)	2025	December		Y

		NHSE (delegated, renal cell carcinoma)				

Patent Expiries 2026

Drug	*BNF*	*Commissioner*	*Loss of exclusivity year*	*Loss of exclusivity month*	*Notes*	*Generic/ biosimilar available or in development*
Ipilimumab	8	NHSE (delegated)	2026	February	Loss of exclusivity date could be later (2037) for colorectal cancer indication which may be covered by an additional patent. SPS is considering developing website content to support implementation.	Y
Susoctocog alfa	9	NHSE (delegated)	2026	February	Loss of exclusivity date highly uncertain	
Saxagliptin/ metformin *(Komboglyze)*	6	ICB	2026	March	Challenges to patent may mean loss of exclusivity occurs earlier in October 2024	
Simoctocog alfa	9	NHSE (delegated)	2026	March		
Nintedanib (*Ofev*)	3	NHSE (delegated)	2026	April		Y
Nintedanib *(Vargatef)*	8	NHSE (delegated)	2026	April		Y
Pitolisant	4	ICB	2026	April	Loss of exclusivity date could be delayed (to April 2027) if additional year of market exclusivity granted by MHRA.	Y
Vedolizumab (intravenous)	1	ICB	2026	April	Potential for extension to October 2026. For the subcutaneous product, loss of exclusivity could be delayed until 2032, depending on legal challenges. SPS is considering developing website content to support implementation.	Y
Belatacept	8	NHSE (retained)	2026	May	Potential for extension to October 2026	
Bromfenac	11	ICB	2026	May		

Conestat alfa	3	NHSE (delegated)	2026	May		
Perampanel	4	ICB	2026	June	Potential for extension to December 2026, possibly applies to tablets only	Y
Fampridine	8	NHSE (delegated)	2026	July		Y
Pasireotide	6	NHSE (delegated)	2026	July	Applies to both pasireotide diaspartate and pasireotide pamoate	
Brivaracetam	4	ICB	2026	August		
Panobinostat	8	NHSE (delegated)	2026	August		
Rilpivirine (*Edurant*)	5	NHSE (delegated, adults) NHSE (retained, children)	2026	November	Potential for extension to May 2027	
Tafamidis	9	NHSE (retained)	2026	November	Applies to hereditary transthyretin amyloidosis (ATTR) only. Wild-type ATTR is protected until at least 2030.	
Tenofovir disoproxil/ emtricitabine/ rilpivirine (*Eviplera*)	5	NHSE (delegated)	2026	November		Y
Azilsartan	2	ICB	2026	December	Potential for extension to June 2027	
Belimumab	10	NHSE (delegated)	2026	December		
Macitentan	2	NHSE (retained)	2026	December	Potential for extension to June 2027 but an additional patent relating to use as combination therapy may extend to August 2027	
Mepolizumab	3	NHSE (delegated)	2026	December	Additional patents may protect beyond this date to 2036.	Y