SUMMARY OF RECOMMENDATIONS FOR HNY-WIDE CONSULTATION

Recommendations agreed for consultation by HNY APC:	06 November 2024
Consultation to run for 4 weeks from	18 November 2024

Local Recommendations

Drug and indication	Rationale / criteria	Status and formulary position proposed	Notes on decision	Cost impact	Commissioning / service implications
None in November 2024					

NICE Technology Appraisals and Guidance

NICE Technology appraisal or guidance	Status and formulary position assigned	Notes on decision	Cost impact	Commissioning / service implications
TA999: Vibegron for treating symptoms of overactive bladder syndrome **4th September 2024** **Commissioning: ICS, 30 day TA** Vibegron is recommended as an option for treating the symptoms of overactive bladder syndrome in adults. It is only recommended if antimuscarinic medicines are not suitable, do not work well enough or have unacceptable side effects.	Add to formulary as a GREEN (with guideline) drug in this indication, alongside mirabegron, with links to TA999 Both NY&Y and Humber OAB guidelines are due for review and will be added to the APC subgroup workplan.	IPMOC October meeting approved a decision made by NY&Y APC to add to formulary as green, alongside mirabegron. Not reviewed by Humber APC. Mirabegron is green and second choice in Humber.	NICE expect the resource impact of implementing the recommendations in England will be around £1,000 per 100,000 population in year 1, increasing to £6,000 per 100,000 population in year 5. This increase is largely driven by population growth, not drug costs. The patent for mirabegron will not expire in the next 2 years.	None expected.

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TA1000: Iptacopan for treating paroxysmal nocturnal haemoglobinuria **4th September 2024** **Commissioning: NHSE** Iptacopan is recommended, within its marketing authorisation, as an option for treating paroxysmal nocturnal haemoglobinuria (PNH) in adults with haemolytic anaemia. Iptacopan is only recommended if the company provides it according to the commercial arrangement.	Add to formulary as a RED drug in this indication, with links to TA1000. The formulary position should reflect the NICE TA as well as any associated NHSE SSCs.		NICE expect the resource impact of implementing the recommendations in England will be less than approximately £8,800 per 100,000 population. This is because PNH is a rare condition and the technology is a further treatment option with the overall cost of treatment for this patient group being unlikely to change significantly with the introduction of iptacopan.	None expected. The National PNH Service is funded by NHS England as a highly specialised service. The service consists of 2 centres, with one based at St James' University Hospital in Leeds and the other based in King's College Hospital in London.
TA1001: Zanubrutinib for treating marginal zone lymphoma after anti-CD20-based treatment **4th September 2024** **Commissioning: NHSE** Zanubrutinib is recommended, within its marketing authorisation, as an option for treating marginal zone lymphoma in adults who have had at least 1 anti-CD20-based treatment. It is only recommended if the company provides it according to the commercial arrangement.	Add to formulary as a RED drug in this indication, with links to TA1001 The formulary position should reflect the NICE TA as well as any associated NHSE SSCs.		The company has a commercial arrangement. This makes zanubrutinib available to the NHS with a discount.	Zanubrutinib is administered orally and will likely reduce the number of intravenous infusions required in treatment when compared with most of the comparator treatments.
TA1002: Evinacumab for treating homozygous familial hypercholesterolaemia in people 12 years and over **11th September 2024** **Commissioning: NHSE** Evinacumab alongside diet and other low-density lipoprotein-cholesterol (LDL-C) lowering therapies is recommended, within its marketing authorisation, as an option for treating homozygous familial hypercholesterolaemia (HoFH) in people 12 years and over. It is only recommended if the company provides it according to the commercial arrangement.	Add to formulary as a RED drug in this indication, with links to TA1002. The formulary position should reflect the NICE TA as well as any associated NHSE SSCs.		A resource impact template is available for local completion. **For adults** Evinacumab is administered by intravenous infusion, which would create an additional administration requirement when compared with its main comparator, lomitapide, which is an oral treatment. But lomitapide use needs quarterly liver function tests and annual liver imaging, which evinacumab does not. **For young people (aged 12 to 17 years)** Lomitapide only has a licence in adults, so the alternative treatment options for young people are limited to lipid-lowering therapies and lipoprotein apheresis. Lipoprotein apheresis is done in lipid clinics and people are usually have treatment biweekly, with treatment duration being 2 to 4 hours. When treatment with evinacumab replaces the need for lipoprotein apheresis, savings from stopping lipoprotein apheresis treatment would arise. But, because evinacumab is administered by intravenous infusion, there would be an additional administration requirement for every young person treated with evinacumab.	

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TA1003: Exagamglogene autotemcel for treating transfusion-dependent beta-thalassaemia in people 12 years and over **11th September 2024** **Commissioning: NHSE** Exagamglogene autotemcel (exa-cel) is recommended with managed access as an option for treating transfusion-dependent beta-thalassaemia in people 12 years and over: • when a haematopoietic stem cell transplant (HSCT) is suitable, but a human leukocyte antigen-matched related haematopoietic stem cell donor is not available • only if the conditions in the managed access agreement for exa-cel are followed.	Add to formulary as a RED drug in this indication, with links to TA1003. The formulary position should reflect the NICE TA as well as any associated NHSE SSCs.		Evidence from an indirect comparison showed that exa-cel reduced the need for transfusions compared with standard care. In the long term, the resource benefits of this could be considerable when compared with the number of years people have regular blood transfusions, and the associated capacity impact avoided. For more information about the treatments, such as dose and average treatment duration, see the resource impact template. While there are additional treatment costs and capacity impacts for people having exa-cel, these are experienced over the year of treatment. These are alleviated by the longer-term benefits from reduced need for regular transfusions.	
TA1004: Faricimab for treating visual impairment caused by macular oedema after retinal vein occlusion **11th September 2024** **Commissioning: ICS, tariff-excluded, 30-day TA** Faricimab is recommended, within its marketing authorisation, as an option for treating visual impairment caused by macular oedema after central or branch retinal vein occlusion in adults. It is only recommended if the company provides it according to the commercial arrangement.	On formulary in Humber and NY&Y as a RED drug per NICE TAs 799 (DMO) and 800 (wet AMD). Retain RED status and update formulary with links to TA1004.	Input is requested from the system on where faricimab should be placed in the treatment pathway	Review ophthalmology pathways to determine place in therapy. Visual impairment caused by macular oedema after retinal vein occlusion is usually treated with anti-VEGF treatments aflibercept and ranibizumab. Faricimab is another treatment option that works in a similar way to aflibercept and ranibizumab and would be offered to the same population. A cost comparison by NICE suggests faricimab has similar costs and overall health benefits to aflibercept. In addition, a majority of people currently have aflibercept for this condition, particularly people starting treatment. So faricimab is recommended as an additional treatment option. The list price of faricimab is £857 for 1 vial of 120 mg per 1 ml solution for injection (excl VAT). The company has a commercial arrangement which makes faricimab available to the NHS with a discount. The size of the discount is commercial in confidence. The availability of biosimilars could lead to significant financial implications. Ranibizumab is already available as a biosimilar. A biosimilar of aflibercept is expected in 2025.	

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TA1005: Futibatinib for previously treated advanced cholangiocarcinoma with FGFR2 fusion or rearrangement **11th September 2024** **Commissioning: NHSE** Futibatinib is recommended, within its marketing authorisation, as an option for treating locally advanced or metastatic cholangiocarcinoma with a fibroblast growth factor receptor 2 (FGFR2) fusion or rearrangement that has progressed after at least 1 line of systemic treatment in adults. Futibatinib is only recommended if the company provides it according to the commercial arrangement.	Add to formulary as a RED drug in this indication, with links to TA1005. The formulary position should reflect the NICE TA as well as any associated NHSE SSCs.		NICE expect the resource impact of implementing the recommendations in England will be less than approximately £8,800 per 100,000 population. This is because the technology is a further treatment option and the overall cost of treatment will be similar for this population.	
TA1007: Rucaparib for maintenance treatment of relapsed platinum-sensitive ovarian, fallopian tube or peritoneal cancer **17th September 2024** **Commissioning: NHSE, 30-day TA** Rucaparib is recommended, within its marketing authorisation, as an option for the maintenance treatment of relapsed platinum-sensitive high-grade epithelial, ovarian, fallopian tube or primary peritoneal cancer that has completely or partially responded to platinum-based chemotherapy in adults. Rucaparib is only recommended if the company provides it according to the commercial arrangement. This appraisal updates and replaces TA611 (November 2019)	Remove links to TA611 and replace with links to TA1007. The formulary position should reflect the NICE TA as well as any associated NHSE SSCs.		The list price of rucaparib is £3,562 per 60-tablet pack of 300-mg, 250-mg or 200-mg tablets (excluding VAT, BNF online, accessed August 2024). The company has a commercial arrangement. The size of the discount is commercial in confidence.	

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TA1008: Trifluridine–tipiracil with bevacizumab for treating metastatic colorectal cancer after 2 systemic treatments **25th September 2024** **Commissioning: NHSE** Trifluridine–tipiracil with bevacizumab is recommended, within its marketing authorisation, for treating metastatic colorectal cancer in adults who have had 2 lines of treatment (including fluoropyrimidine-, oxaliplatin- and irinotecan-based chemotherapies, antivascular endothelial growth factor or anti-epidermal growth factor receptor treatments). Trifluridine–tipiracil with bevacizumab is only recommended if the company provides trifluridine–tipiracil according to the commercial arrangement.	Add to formulary as a RED drug in this indication, with links to TA1008. The formulary position should reflect the NICE TA as well as any associated NHSE SSCs.		There is no additional infrastructure that needs to be put in place, and there are no anticipated implementation issues. There will be a capacity increase because the treatment duration for trifluridine–tipiracil with bevacizumab is greater than that for comparators. Also, bevacizumab is delivered intravenously, whereas comparator treatments are delivered orally.	
All links to MHRA drug safety updates added to formulary as published. Significant alerts where further action is required are highlighted.				

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