North Yorkshire & York Area Prescribing Committee

Summary of decisions made regarding new product requests considered at a meeting of the Committee on the 3rd August 2022

Classification of products:

G **Green drug** - Can be initiated and prescribed in all care settings O- Second line / alternative green drug

ASR **Amber Specialist Recommendation drug -** Can be recommended by a specialist for initiation in primary care

ASI **Amber Specialist Initiation drug** – Initiated by a specialist and transferred to primary care once the patient stabilised. In some cases there may be a further restriction for use outlined - these will be defined in each case.

ASC **Amber Shared Care drug** - These are specialist drugs which must be initiated by the specialist, but with the potential to transfer to primary care within written and agreed shared care protocols and according to the agreed process for transfer of care

R **Red drug** - Drugs that should remain under the total responsibility of the specialist. Usually considered as "hospital only" drugs

BLACK **Not Approved** - Drugs that have been considered by the APC or other approved body and are not approved for prescribing within North Yorkshire & York.

GREY **Not Reviewed** - Drugs that have not been reviewed by the APC yet. This usually means that no application has been received or that an application is in progress. These drugs are not normally considered appropriate for prescribing in North Yorkshire & York.

Product	Decision			Comments/notes
	Approved	Refused	Deferred	
1) Requests deferred from previous meeting				
Lyumjev® Insulin	✓ ASI			**Decision:** approved for the treatment of diabetes mellitus in adults only as per licensed indication. Second line after rapid acting analogue insulins. To be considered if post prandial hyperglycaemia (>9mmol/L 2 hours post meal) or patient unable to adhere to current insulin regimen by pre bolusing prior to meals (for example due to work related constraints) Fiasp® to remain on formulary because there may be patients who are unresponsive to Lyumjev® or allergic to Lyumjev®.
TA791: Romosozumab for treating severe osteoporosis	✓ R			The formulary will reflect the TAG – **ICS** is the responsible commissioner. Noted regional pathway in development. Until then will be used as per SIGN guidance.

Product	Decision			Comments/notes
	Approved	Refused	Deferred	
2) New Requests				
Oral Minoxidil for Female pattern hair loss		✓		**Decision:** application refused on grounds of equality as application does include use in males. Also noted that topical forms are not approved on basis not a good use of NHS resources but unlike oral minoxidil they are available to purchase over the counter. APC would accept a resubmission for use in both females and males.

Cyclogest® progesterone pessaries for miscarriage	✓ R			**Decision:** approved for use as per NICE guidance for:
				• Patients with a confirmed intrauterine pregnancy presenting with bleeding in the first trimester of pregnancy with any history of previous miscarriage (not just recurrent miscarriage)
				• Patients with high risk of preterm labour
				  ○ previous late miscarriage preterm labour (16-34 weeks) or
				  ○ short cervix on US scan (cervical length of 25 mm or less) performed (16-26 weeks)
				Agreed that these patients should be under specialist care and review, and that GPs should not be asked to prescribe for these indications.

Glucagon prefilled pen (Ogluo®)		✓		Requested for treatment of severe hypoglycaemia in children aged 2 years and over with diabetes mellitus. To be used in childrens services only. **Decision:** application refused on basis of significant cost difference over current Glucagen® product and no evidence presented of critical incidents due time to reconstitute current product.
Hydrocortisone MR (Efomdy®)			✓	Requested for treatment of Congenital Adrenal Hyperplasia (CAH) in adolescents aged 12 years and over and adults. This delayed release formulation enables diurnal rhythm matching of cortisol release to avoid early morning rises of active hormones as well as preventing the night time insomnia and sleep difficulties encountered in current steroid practice. Decision deferred to fully appraise evidence around diurnal variation and steroid sparing effect.
3) New formulations & extensions to use				
Nil this month				

Product	Decision			Comments/notes
	Approved	Refused	Deferred	
5) Products considered by NICE				
TA792 Filgotinib for treating moderately to severely active ulcerative colitis	✓ R			The formulary will reflect the TAG – ICS is the responsible commissioner.
TA793 Anifrolumab for treating active autoantibody-positive systemic lupus erythematosus (terminated appraisal)	✓ BLACK for this indication			The formulary will reflect the TAG – ICS is the responsible commissioner.
TA794 Diroximel fumarate for treating relapsing–remitting multiple sclerosis	✓ R			The formulary will reflect the TAG – NHS England is the responsible commissioner.
TA795 Ibrutinib for treating Waldenstrom's macroglobulinaemia	✓ BLACK for this indication			The formulary will reflect the TAG – ICS is the responsible commissioner.
TA796 Venetoclax for treating chronic lymphocytic leukaemia	✓ R			The formulary will reflect the TAG – NHS England is the responsible commissioner.
TA797 Enfortumab vedotin for previously treated locally advanced or metastatic urothelial cancer (terminated appraisal)	✓ BLACK for this indication			The formulary will reflect the TAG – ICS is the responsible commissioner.
TA798 Durvalumab for maintenance treatment of unresectable non-small-cell lung cancer after platinum-based chemoradiation	✓ R			The formulary will reflect the TAG – NHS England is the responsible commissioner.
TA799 Faricimab for treating diabetic macular oedema	✓ R			The formulary will reflect the TAG – ICS is the responsible commissioner.
TA800 Faricimab for treating wet age-related macular degeneration	✓ R			The formulary will reflect the TAG – ICS is the responsible commissioner.

DECISION SUMMARY

Product	Decision			Comments/notes
	Approved	Refused	Deferred	
TA801 Pembrolizumab plus chemotherapy for untreated, triple-negative, locally recurrent unresectable or metastatic breast cancer	✓ R			The formulary will reflect the TAG – NHS England is the responsible commissioner.
TA802 Cemiplimab for treating advanced cutaneous squamous cell carcinoma	✓ R			The formulary will reflect the TAG – NHS England is the responsible commissioner.
TA804 Teduglutide for treating short bowel syndrome	✓ R			The formulary will reflect the TAG – NHS England is the responsible commissioner.
6) Appeals against earlier decisions by the APC				
None				
7) Miscellaneous formulary decisions by the APC				
Fidaxomicin (Dificlir® 40mg/ml granules for oral suspension	✓ ASI			**Decision:** approved. A new liquid formulation of fidaxomicin. It is licensed for oral administration and also for administration via feeding tubes.
Sacubitril/Valsartan RAG review	✓ ASR			**Decision:** change in formulary RAG status from AMBER Specialist Initiation to AMBER Specialist Recommendation approved in order that GPs may continue prescribing after a full review by a heart failure nurse who may not be a non-medical prescriber.

The following guidelines were presented to and approved at the August 2022 meeting of the APC:

- NY&Y Biologics pathway for Crohn's Disease and UC

The following guidelines were presented to and recommended for approval to the HNY IMOC at the August 2022 meeting of the APC:

- Type 2 diabetes guidance incorporating earlier place in therapy of SGLT2 inhibitors

The following shared care guidelines were presented to and received for information at the August 2022 meeting of the APC:

- Nil this month.