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## **Update to Near Patient Testing – Amber Drugs Service Specification**

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### **Background:**

#### **National Context**

The treatment of several diseases within the fields of medicine, particularly in rheumatology and psychiatry, is increasingly reliant on drugs that while clinically effective, need regular blood tests or other investigations such as ECG or blood pressure monitoring. This is due to the potentially serious side-effects that these drugs can occasionally cause. It has been shown that the incidence of side-effects can be reduced significantly if this monitoring is carried out in a well-organised way, close to the patient's home.

Prior to April 2013, a local adaptation of a National Enhanced Service for Near Patient Testing (NPT) defined what drugs were included within the service, general detail of the expected safety and partnership working requirements of the service, the agreed banding of different drugs and the payments the bands would attract.

For many diseases a drug's effectiveness is monitored by hospital specialists while the prescribing and monitoring for side effects is done by the GP. This organised model is typically delivered under a shared care arrangement, with clear and locally agreed guidelines (SCGs) between hospital and primary care representatives. Drugs that fall into this category are locally called 'amber – shared care' (amber-SC). For many drugs there may be a greater level of baseline testing and monitoring involved before the GP is asked to take on prescribing and more routine monitoring.

Another 'amber' category exists for drugs that require initiation either by an appropriate hospital specialist or on their recommendation. These drugs do not require SCGs because any monitoring requirements are considered as relatively standard primary care activity. Red drugs, however, should only be prescribed within the hospital by appropriate specialists but GPs will be informed of the drugs involved and the progress in the management of the patient's disease. Green drugs are those that can typically be initiated in primary care by the patient's GP or another prescriber.

Many SCGs exist, with variation influenced by the side effect profile of the drug, the condition being treated (with different tolerance levels and doses being used) and between hospitals. It should be expected that specialist teams in different hospitals may not all delegate the monitoring requirements to GPs in the same way. It is also noted that green and non-shared care amber drugs can require monitoring and if this is significant for GP practices then they should be considered for inclusion in this service.

## **Local Context**

NHS Vale of York Clinical Commissioning Group benefits from a close working relationship with the main local providers of York Teaching Hospital NHS Foundation and Tees, Esk and Wear Valleys NHS Foundation Trust. Joint decision making and partnership working at the local Medicine Commissioning Committee supports the timely transfer of some of the regular drug monitoring requirements of patient's treatments to their GP. The Medicine Commissioning Committee will determine if a drug is suitable for shared care and generate drug specific shared care guidelines to explicitly define the roles and relationships between the GPs and hospital specialists. Vale of York Clinical Commissioning Group will then agree in partnership with local primary care providers through their representative body (Local Medical Committee), how much work is involved for the GP practice and the corresponding payment this work should attract.

At Clinical Commissioning Group level, the overall level of payment can be influenced by factors such as drugs moving from one payment band to another, changes in local specialists prescribing patterns and pathways of care, e.g. NICE guidance and drugs being removed or added to lists. It is important to ensure that prescribing and monitoring that is suitable for primary care does not get blocked into secondary care which would be inconvenient for patients and unnecessarily expensive for Vale of York Clinical Commissioning Group.

From April 2013, the funding of some of the more specialist drugs shifted to NHS England. Where these treatments are only provided within secondary care, Vale of York Clinical Commissioning Group does not incur costs. In localities within the NHS, some of these drugs are still managed under shared care arrangements. Until funding and prescribing arrangements are transferred, the Clinical Commissioning Group and hospital trusts will continue to ensure safe prescribing and monitoring is applied

## **Action for Primary Care Commissioning Committee**

The four North Yorkshire CCG's, have proposed to align the banding criteria and the drugs within these. It has been proposed that Vale of York and the other North Yorkshire CCGs move to the same banding criteria as Hambleton, Richmondshire and Whitby CCG (HRW). – see appendix 1

Harrogate and Rural District CCG and Vale of York Medicines Management Team (MMT) have commented on the service specification drugs for Vale of York CCG (VoY), Harrogate and Rural District CCG (HaRD), Scarborough and Ryedale CCG (SR) and Hambleton, Richmondshire and Whitby CCG. The MMT have supported the evaluation of what monitoring is required for each drug and hence why each drug should be placed in the different bands.

The above require consideration by the Primary Care Commissioning Committee.

## Proposed banding criteria

Banding	Payment per drug patient	Typical monitoring
Band 1	£91.95	high intensity monitoring
Band 2	£45.97	intermediate
Band 3	£7.15	closer to routine and/or infrequent

Table1: VoY CCG Banding criteria and service payments for 'Monitoring of Drugs in Primary Care'

Table 1 shows the current bandings for the VoY CCG and HaRD CCG. SRCCG currently does not have a 'Monitoring of drugs in Primary Care' local enhanced scheme.

The new payment banding criteria introduces the 'band 2b' for anti-psychotics drugs which attracts a lower payment of £26.56 (as opposed to the current £45.97 in VoY and HaRD). This is the current banding criteria for HRW CCG (Table 2). The current higher rate of £45.97 is paid for anti-psychotics drugs monitoring of patients on QOF mental health register. The new payment of £26.56 is for all patients on anti-psychotics who require monitoring, regardless of whether they are on the QOF mental health register. Moving to this banding criteria, will allow consistent remuneration for primary care providers across the NY CCG's and would be a cost saving for VoY CCG.

It should be noted that the four NYCCG's are also proposing to introduce a local enhanced scheme for physical health checks for patients with serious mental illness, subject to approval. This would attract a payment of £11.50 per activity on top of any payment made for anti-psychotic drug monitoring. This may be an additional cost pressure to VoY CCG on the current payment of £45.97 but a lower cost pressure on the new band 2b payment of £26.56.

Banding	Payment per drug patient per year	Typical monitoring requirements
Band 1	£91.95	high intensity monitoring
Band 2a	£45.97	intermediate
Band 2b	£26.56	anti-psychotics
Band 3	£7.15	closer to routine and/or infrequent

Table 2: HRW CCG Banding criteria and service payments for 'Monitoring of Drugs in Primary Care'

## Proposed changes within banding criteria

The amber drugs list within the bands have been amended to form one single list for all NY CCGs to ensure all primary care providers, deliver appropriate monitoring of the relevant drugs (see appendix 2). The summary of the changes can be seen below.

Tacrolimus(po)	From band 1 to band 2 - In line with frequency of monitoring
Sirolimus(po)	From band 1 to band 2 - In line with frequency of monitoring
Degarelix(inj)	From band 2 to band 1 - As it requires monthly administration
Testosterone(inj)	From band 2 to band 3 - In line with HRW and new for HaRD
Amisulpiride (po)	From band 2 to band 2b – New band for anti-psychotics
Aripiprazole (po/inj)	
Benperidol (po)	
Chlorpromazine (po)	
Flupentixol (inj)	
Fluphenazine (inj)	
Haloperidol (po)	
Olanzapine (po)	
Pericyazine (po)	
Pimozide (po)	
Quetiapine (po)	
Risperidone (po/inj)	
Sulpiride (po)	
Trifluoperazine (po)	
Zuclopenthixol (po)	
Zuclopenthixol Decanoate	
Tolcapone	Added to band 1- To be paid where it is locally commissioned
Guanacine (po)	Added to band 2 – New shared care drug
Entacavir	Added to band 2 - Only if initiated under the Leeds shared care agreement for all the NYCCGs
Lamivudine	
Tenofovir	
Flupentixol (inj)	Added to band 2b - To be in line with other NY CCGs
Paliperidone (po/inj)	Added to band 2b – New shared care drug
Promazine (po)	Added to band 2b - To be in line with other NY CCGs
Flutamide (po)	Removed from Band 2 - To be in line with other NY CCGs and
Hydroxycarbamide (po)	Removed from Band 2 – To be in line with other NY CCGs
Somatropin (inj)	Removed from Band 2 – To be in line with other NY CCGs
Topiramate (po)	Removed from Band 2 – Not shared care/ minimal monitoring
Vigabatrin (po)	Removed from Band 2 - Not shared care/ minimal monitoring
Perphenazine (po)	Removed from Band 2 – Drug discontinued

**The estimated cost saving of moving to the proposed North Yorkshire CCG service spec for the Vale of York CCG: ~£69,132.67 per annual**

**Explanation of Calculation/Estimation of Cost Impact**

The calculation for drugs that are moving banding is based on how many existing claims Vale of York receive for those drugs, i.e. we know the number of existing patients and can calculate based on banding price increase (or decrease).

The calculation for the additional drugs is estimated. It is known how many patients are on these drugs for SystOne practices, a search can be completed for number of patients that currently have these drugs on their repeat template. The same search cannot be completed for EMIS Web practices and hence can only be estimated by scaling up from the SystmOne Figures - SystmOne covers 214,000/350,000 Vale of York population. The actual may be more or less.

**Moved Bandings Calculation**

Moved bandings for VoY	Patient From S1 Report tool Population 214,000	Patients Scaled up for VoY Population 350,000	Previous Banding cost	Previous cost	New banding cost	New cost	Cost difference
<b>From 1 to 2</b>							
Tacrolimus(po)	1	1.6355	£91.95	£150.39	45.97	75.184579	-£75.20
Sirolimus(po)	7	11.449	£91.95	£1,052.70	45.97	526.29206	-£526.41
<b>From 2 to 1</b>							
Degaralix(inj)	2	3.271	£45.97	£150.37	£91.95	300.77103	£150.40
<b>From 2 to 3</b>							
Testosterone(inj)	67	109.58	£45.97	£5,037.37	£7.15	783.49299	-£4,253.87
<b>From 2 to 2b(new)</b>							
Amisulpiride (po)	52	85.047	£45.97	£3,909.60	£26.56	2258.8411	-£1,650.76
Aripiprazole (po/inj)	171	279.67	£45.97	£12,856.56	£26.56	7428.1121	-£5,428.45
Benperidol (po)	1	1.6355	£45.97	£75.18	£26.56	43.439252	-£31.75
Chlorpromazine (po)	31	50.701	£45.97	£2,330.72	£26.56	1346.6168	-£984.11
Flupentixol (inj)	10	16.355	£45.97	£751.85	£26.56	434.39252	-£317.45
Fluphenazine (inj)	1	1.6355	£45.97	£75.18	£26.56	43.439252	-£31.75
Haloperidol (po)	67	109.58	£45.97	£5,037.37	£26.56	2910.4299	-£2,126.94
Olanzapine (po)	495	809.58	£45.97	£37,216.37	£26.56	21502.43	-£15,713.94
Pericyazine (po)	3	4.9065	£45.97	£225.55	£26.56	130.31776	-£95.24
Pimozide (po)	1	1.6355	£45.97	£75.18	£26.56	43.439252	-£31.75
Quetiapine (po)	385	629.67	£45.97	£28,946.06	£26.56	16724.112	-£12,221.95
Risperidone (po/inj)	192	314.02	£45.97	£14,435.44	£26.56	8340.3364	-£6,095.10

Sulpiride (po)	29	47.43	£45.97	£2,180.35	£26.56	1259.7383	-£920.61
Trifluoperazine (po)	16	26.168	£45.97	£1,202.95	£26.56	695.02804	-£507.93
Zuclopenthixol (po)	21	34.346	£45.97	£1,578.88	£26.56	912.2243	-£666.65
Zuclopenthixol Decanoate (inj)	6	9.8131	£45.97	£451.11	£26.56	260.63551	-£190.47
							<b>-£51,719.91</b>

### Additional Drugs Calculation

Additional drugs for VoY Banding	From S1 Report tool Population 214,000	Scaled up for VoY Population 350,000	New banding cost	New cost
<b>Band 1</b>				
Tolcapone	0	0	£91.95	£0.00
<b>Band 2</b>				
Guanacine (po)	1	1.6355	£45.97	£75.18
Entacavir	0	0	£45.97	£0.00
Lamivudine	2	3.271	£45.97	£150.37
Tenofovir	0	0	£45.97	£0.00
<b>Band 2b</b>				
Flupentixol (inj)	17	27.804	£26.56	£738.47
Paliperidone (po/inj)	0	0	£26.56	£0.00
Promazine (po)	1	1.6355	£26.56	£43.44
				<b>£1,007.46</b>

Drugs removed from VoY Banding	From S1 Report tool Population 214,000	Scaled up for VoY Population 350,000	Previous Banding cost	Previous cost
<b>Band 2</b>				
Flutamide (po)	0	0	£45.97	£0.00
Hydroxycarbamide (po)	39	63.785	£45.97	£2,932.20
Somatropin (inj)	0	0	£45.97	£0.00
Topiramate (po)	204	333.64	£45.97	£15,337.65
Vigabatrin (po)	2	3.271	£45.97	£150.37
Perphenazine (po)	0	0	£45.97	£0.00
				<b>-£18,420.22</b>



**Total = Changed Bandings plus Additional Drugs**

	VoY
<b>Changed bandings</b>	-£51,719.91
<b>Additional drugs</b>	£1,007.46
<b>Drugs Removed</b>	-£18,420.22
	<b>-£69,132.67</b>

**Summary of Options**

Option Title	Advantages/ Benefits	Disadvantages/ Constraints	Recommended Y/N
1. Do nothing	No cost impact	<ul style="list-style-type: none"> <li>Not supporting primary care providers to provide appropriate monitoring of required drugs. The evidence that the incidence of side effects can be reduced significantly if this monitoring is carried out using an organised system closer to the patient's home (rather than in hospital). Therefore greater risk of patient harm.</li> <li>Risk that prescribers will refuse to take on the prescribing of these drugs – either patient required to travel to secondary care providers – inconvenience for patients and greater cost for CCG OR patients do not receive the drugs they require.</li> </ul>	No
2. Move to updated spec with new banding criteria	<ul style="list-style-type: none"> <li>Cost saving ~<b>£69,132.67</b></li> <li>Aligns all NYCCG specs</li> <li>Supports primary care providers to provide appropriate monitoring of required drugs. The evidence that the incidence of side effects can be reduced significantly if this monitoring is carried out using an organised system closer to the patient's home (rather than in hospital).</li> <li>Reduces risk that prescribers will refuse to take on the prescribing of these drugs especially if all of NYCCG have the same drugs on the spec and are equally remunerated for the monitoring</li> </ul>		Yes

**Action for Primary Care Commissioning Committee**

Primary Care Commissioning Committee are requested to:

- ✓ Consider options as presented above in summary of options

**ENDS**

## Appendix 1:

### Banding criteria and service payments for 'Monitoring of Drugs in Primary Care'

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The following general definitions are used to assist determination of which banding specific drugs will fall into. The detail below is NOT the definition of monitoring requirements for each drug within that banding. For monitoring requirements for each drug, please refer to the current monitoring or shared care guidelines for the drug (or group of drugs) from the relative hospital provider.

**Band 1: £91.95 per drug per patient per year**

Monitoring every one-two months of U&Es, LFTs, FBCs.

Include ECG, respiratory function tests etc. more than once a year.

Verbal interview and record keeping of symptom checklist.

Reporting of concerns to specialist.

**Band 2: £45.97 per drug per patient per year**

Monitoring more than twice a year up to and including every three months.

Include ECG, respiratory function tests etc. once a year.

Verbal interview and record keeping of symptom checklist.

Reporting of concerns to specialist.

**Band 2b: £26.56 per drug per patient per year**

**Excluding the use of these drugs for end of life care**

Monitoring typically twice a year but may be up to and including every three months.

Include ECG, respiratory function tests etc. once or twice a year in relevant patients.

Verbal interview and record keeping of symptom checklist.

Reporting of concerns to specialist.

**Band 3: £7.15 per drug per patient per year**

Monitoring twice a year or less often

Two or more of the following: U&Es, LFTs, FBCs

Verbal interview and record keeping of symptom checklist.

Reporting of concerns to specialist.

## Appendix 2:

### **Banding decisions on drugs included in the 'Monitoring of Drugs in Primary Care' service**

Many current versions of monitoring or shared care guidelines can be accessed at relevant hospital trust websites:

- Tees, Esk & Wear Valleys NHSFT at <http://www.tewv.nhs.uk/site/content/About/How-we-do-it/Policies/Pharmacy-policies-and-pr>
  - Antipsychotic monitoring requirements (under Clinical medication guidelines)
  - Formulary and safe transfer of prescribing (under Shared care and transfer of prescribing)
- South Tees NHS Foundation Trust: [www.southteesformulary.nhs.uk/](http://www.southteesformulary.nhs.uk/)
- County Durham and Darlington: <http://formulary.cdd.nhs.uk/>
- York and Scarborough Formulary: [www.yorkandscarboroughformulary.nhs.uk/](http://www.yorkandscarboroughformulary.nhs.uk/)
- Harrogate Formulary: <http://www.harrogateformulary.nhs.uk/>
- Leeds Formulary: <http://www.leedsformulary.nhs.uk/default.asp>
- Newcastle Formulary: <http://www.northoftyneapc.nhs.uk/shared-care-group/>

#### **Band 1:**

**Frequent blood testing**, in respect of the following specified drugs:

Azathioprine (po)	Ciclosporin (po)
Degarelix (inj)	Leflunomide (po)
Mercaptopurine (po)	Methotrexate (po and s/c if commissioned)
Mycophenolate (po)	Penicillamine (po)
Sodium aurothiomalate (inj)	Sulphasalazine (po)
Tolcapone (po) – where locally commissioned	

#### **Band 2:**

**Monitoring, including blood testing, or other special monitoring or other special circumstances**, in respect of the following drugs:

Atomoxetine (po)	Denosumab (inj)
Dexamfetamine (po)	Dronedarone (po)
Goserelin (imp)	<u>Gaunfacine (po)</u>
Leuprorelin (inj)	Lisdexamphetamine (po)
Methylphenidate (po)	Riluzole (po)
<u>Sirolimus (po)</u>	Tacrolimus (po)
Triptorelin (inj)	

Entecavir/Lamivudine/Tenofovir disoproxil fumarate **only** when prescribed under a shared care agreement with Leeds Teaching Hospitals NHS Trust

#### **Band 2b:**

**Anti-psychotics (excluding when used for end of life care)**, in respect of the following drugs:

Amisulpiride (po)	Aripiprazole (po and depot)
Benperidol (po)	Chlorpromazine (po)
Flupentixol (po/ inj)	Fluphenazine (inj)
Haloperidol (po)	Olanzapine (po)
Paliperidone (po and depot injection)	Pericyazine (po)
Pimozide (po)	Promazine (po)

Quetiapine (po)  
Sulpiride (po)  
Zuclopenthixol (po)

Risperidone (po and inj)  
Trifluoperazine (po)  
Zuclopenthixol (decanoate inj only)

**Band 3:**

**Routine monitoring of the following drugs:**

Amiodarone (po)  
Darbepoetin alfa (inj)  
Epoetin (inj)  
Hydroxychlorquine sulphate (po)  
Lanreotide (inj)  
Modafinil (po)  
Rivastigmine (po)

Apomorphine (inj)  
Donepezil (po)  
Galantamine (po)  
Ibandronic acid (po once daily prep.) ‡  
Memantine (po)  
Octreotide (inj)  
Testosterone (inj only)

‡ In the management of post-menopausal women with breast cancer initiated on ibandronic acid 50mg by secondary care specialists to improve breast cancer survival. Ibandronic acid is unlicensed for this indication.

Additions which are new for all CCGs in 2019/20 are underlined.

Please note that this document is an amalgamation of the versions previously in use in HRW, HaRD, VoY and ScR and so some medicines may appear in different bands.