



Commissioning for Quality in Medicines Optimisation

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CONSULTATION AND RATIFICATION SCHEDULE

Name and Title of Individual	Date Consulted
V1 Manir Hussain Associate Director of Medicines Optimisation	

Name of Committee	Date of Committee
CCG Joint Medicines Optimisation Committee	16 th March 2016
CCG Joint Planning Committee	10 th May 2016
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Commissioning for Quality in Medicines Optimisation

Medicines Optimisation

1. The use of medicines is the most common treatment intervention within the NHS. Medicines bring enormous benefits to patients and the NHS but also pose significant clinical and financial risk to NHS organisations and health economies. Medicines must therefore be used responsibly across health economies so that patients and NHS organisations utilise medicines safely, effectively and efficiently.
2. Significant progress has been made with medicines optimisation services in recent years and this is detailed in publications produced by the National Audit Office, Care Quality Commission, National Patient Safety Agency and the National Institute for Health and Clinical Excellence (NICE), which further identify areas which NHS organisations might improve.

General Requirements

3. The contractual requirements in this section are to satisfy the Commissioner that the medicines optimisation services provided are fit for purpose and demonstrate that the Provider has a clear understanding of how medicines are utilised within their Trust and that the associated administrative processes are efficient.
4. The Provider will develop and maintain organisational policies that reflect the standards of care and patient safety that might reasonably be expected from such a Provider and ensure that policies and procedures are effectively communicated throughout the Trust, paying due regard to NICE Guideline 5, Medicines Optimisation, March 2015.
5. Such policies may be developed in accordance with information published by NICE, DH, or other professional body eg. British Oncology Pharmacy Association
6. The Provider must comply with the Royal Pharmaceutical Society Professional Standards for Hospital Pharmacy Service, Version 2, July 2014 or any subsequent guidance issued superseding this.
7. The Provider must comply with the General Medical Council "Good Practice in Prescribing" Supplementary Guidance 2013 or any subsequent guidance issued superseding this.
8. The Provider will ensure that all relevant clinicians abide by the Care Quality Commission Essential Standards of Quality and Safety, Outcome 9: Management of Medicines 2010. This outcome related to Regulation 13 of the Health and Social Care Act 2008 (regulated Activities) Regulations 2010, or any subsequent guidance issued superseding this.
9. The Provider shall be responsible for ensuring that all clinicians are aware of the requirements of this section of the contract and where clinically appropriate shall ensure its clinicians comply with the following:
10. The Provider shall be responsible for ensuring that all clinicians are aware of the CCG IFR process and the Policy of Excluded and Restricted Procedures.

Formularies and Prescribing Guidelines

11. The Provider will comply with the Joint Formulary status for drugs reviewed by the NMC and approved by the APC. Drugs classed as “RED” should only be used in secondary care and not recommended for use in primary care. Those with “Amber 1” status should remain in the Provider setting and only transferred into primary care under an agreed ESCA.
12. The Provider shall not ask GPs to prescribe drugs that have undergone review by the New Medicines Committee (NMC) and endorsed by the Area Prescribing Committee (APC) as “RED”. Requests for a GP to prescribe a “GREY” category medicine (i.e. application not supported for inclusion within the Joint Formulary) should not routinely occur.
13. The Provider will ensure all the clinicians are aware of the Joint Formulary and how to access it as well as the process for non-formulary requests.
14. The Provider shall support the Joint Formulary process through attendance at relevant committee meetings as well as upholding internal processes.
15. The Provider will support any locally, regionally or nationally agreed prescribing initiative to improve the quality or cost-effectiveness of prescribing.
16. The Provider shall not ask GPs to prescribe drugs which expert clinical opinion (e.g. MTRAC, NICE) does not recommend for GP use. Similarly the Provider will not initiate and discharge patients with medication which are being used against guidance from NICE, MHRA, CSM, or other national bodies.
17. The Provider shall not request GPs to prescribe drugs for use outside of their licensed indications, unless there is a substantial body of evidence to support the request and this is summarised and shared with the patient’s General Practitioner at the time of request.
18. The Provider shall not ask GPs to prescribe unlicensed drugs¹ except in cases where there is no alternative licensed treatment or off label² treatment suitable for the patient. Unlicensed treatment recommendations must be backed up with clinical evidence or experience with regards to safety and efficacy. Please refer to the CCG Policy on the Commissioning of Medicines.
19. The Provider shall ensure that generic drug names are used except where this is clinically inappropriate e.g. ciclosporin, tacrolimus.
20. The Provider shall not request GPs to prescribe an unlicensed “special” formulation where a suitable proprietary alternative is available.
21. The Provider shall seek to ensure patient engagement and joint decision making with reference to NICE Guideline 5, Medicines Optimisation, March 2015.
22. The Provider shall ensure that the following Department of Health publications are adopted and implemented throughout the life of this contract unless superseded:
 - *Clinical guidelines for immunoglobulin use-second edition update (Nov 2011)*

¹ Unlicensed drugs are defined as drugs which have not been issued with a marketing authorisation in the European Union.

²Off Label treatment is a licensed drug being used outside its licensed indication.

- *Demand management plan for immunoglobulin use (June 2008)*
- *HSC2008/001 relating to safety standards for intrathecal chemotherapy.*

Essential Shared Care Agreements (ESCA):

23. Shared care agreements are used when transferring patients from specialist to general practitioner care, to ensure that all parties are aware of their obligations for monitoring.
24. The use of an ESCA in some cases allows GPs to prescribe specialist drugs and have confidence that the practice is safe and appropriate.
25. ESCAs should be drawn up or adapted by the clinical specialist and presented at the Area Prescribing Committee for approval. The Provider must not distribute ESCAs which have not undergone review by the Area Prescribing Committee and received approval.
26. A GP has the right to refuse to enter into an ESCA. In such an event the specialist retains prescribing responsibility to ensure that the patients care is not interrupted. Invoicing arrangements will need to be agreed with the Commissioner to allow the Provider to recover the drug costs where appropriate.

Managed Entry of New Medicines and NICE Implementation:

27. The Commissioner will not fund high cost medicines/ PbR excluded medicines unless the use has been agreed:
 - a. for inclusion within the Joint Formulary
 - b. via an approved Individual Funding Request (IFR)
 - c. via NICE as a positive Health Technology Appraisal (HTA)
 - d. via an approved local commissioning agreement
28. NICE recommendations on the use of medicines or devices other than an HTA are discretionary and prescribing will need to be agreed with the commissioners.
29. The Provider will act in accordance with national and regional commissioning arrangements. The local CCG will not underwrite any losses incurred by the Provider as a result of failing to act on changes to the commissioning arrangements published nationally i.e. NHSE as Prescribed Specialised Services and Public Health England.
30. New high cost medicines or new indications for existing medicines will automatically be considered as low priority or investment in-year. These medicines will not be routinely available until such a time as their use is commissioned.

PbR Excluded High Cost Medicines:

31. Medicines excluded from PbR are published by the Department of Health and this list is considered to be exhaustive. All other medicines are deemed to be in-tariff unless specifically agreed through the contracting process.
32. Refer to the North Staffordshire CCG and Stoke on Trent CCG Commissioning Policy on the funding of PbR excluded medicines. It is recognised that some PbR excluded high cost drugs associated with specialised services will be commissioned by the NHS National Commissioning Board (see NHS Commissioning Board Manual for prescribed specialised services November 2012 and updates.)
33. From April 2016, the Provider will be required to request approval of all PbR excluded medicines through Blueteq®. This will provide the Trust with assurance the Commissioner will fund the medicine intervention.

34. The Provider is expected to invoice the commissioner for PbR excluded medicines at cost plus VAT other than those supplied through Homecare arrangements which are zero rated for VAT. No on-cost or surcharges should be added unless specifically agreed with the commissioner.
35. The Provider will ensure that costs levied against the Commissioner for PbR excluded drugs relate solely to supplies to patients registered with GP practices within that CCG.
36. The Provider will submit charges for the PbR excluded medicines in accordance with the SUS flex and freeze timetable.

In PbR Tariff Medicines with Specific Agreed Commissioning Arrangements:

37. There are a small number of in-PbR tariff medicines with specific locally agreed commissioning arrangements to support long term prescribing arrangements. These are recognised and documented in the White List ([hyperlink inclusion on ratification of policy](#)).
38. Blueteq® shall be utilised to charge the CCG for the prescribing costs of these agreed medicines.
39. The Provider will submit charges for the PbR excluded medicines in accordance with the SUS flex and freeze timetable.

Patient Access Schemes:

40. For the purpose of this section, a patient access scheme relates to any scheme or agreement entered into by the NHS with a drug manufacturer which applies contingencies on particular drugs availability on the NHS. Some such schemes also form part of NICE technology appraisals.
41. The Provider will ensure that in respect of any contingencies imposed by NICE or the NHS or Commissioner, that all contingencies are fully met and any reimbursements due are claimed and credited to the Commissioner.
42. The Provider will be responsible for devising effective and robust management systems for each scheme and upon request provide evidence that an effective system is in place.

NICE Drugs:

43. The Provider shall conform and adhere where appropriate to a NICE HTA/TAG and use NICE initiation and continuation forms via the Blueteq® system. The Commissioner will seek to recover costs if subsequent evidence identifies use outside of NICE HTA either before or after implementation.
44. The Provider shall maintain adequate records to demonstrate compliance with NICE technology appraisal guidance and make this available to the Commissioner upon request.
45. The Provider shall on request provide evidence of compliance of the above point.
46. The Provider shall bring to the attention of the Commissioner any service, policy or procedure that is not compliant with NICE guidance (including clinical guidelines and interventional procedures).

47. The Provider will adhere to any implementation arrangements agreed by the Health Economy NICE Implementation Group in relation to NICE technology appraisal guidance. Failure to do so will be at the financial risk of the Provider.

Medicines Provision via “Homecare” Companies:

48. It is recognised that in some situations it is considered to be cost-effective and in the patient’s interest to contract with “homecare” providers to deliver drugs to patient’s homes.
49. The Provider must comply with the recommendations of the Hackett Report 2011 *Homecare Medicines – Towards a vision*
50. The Provider shall provide the same standard of gate-keeping for drugs and services commissioned through “homecare” providers as applied to medicines supplied by the Provider directly.
51. The Provider shall devise and implement a system whereby the invoices from the “homecare” suppliers are reconciled against prescriptions and deliveries. Any anomalies shall be queried with the supplier.
52. The Provider will at all times engage with the Commissioners in processes to maximise the cost benefits of homecare provision and award contracts for such provision in accordance with appropriate NHS procurement arrangements

Reporting requirements

53. The Provider shall provide costed patient level monthly information together with prescribed audit requirements for all chargeable medicines which includes those supplied by homecare providers. This will be in accordance with the SUS flex and freeze time table.

Individual Funding Requests (IFRs):

54. The Provider should refer to the CCG IFR Policy and the Policy of Excluded and Restricted Procedures.

Risk and Reward Sharing Schemes:

55. Risk and Reward Sharing Schemes between Provider and Commissioner in the field of medicines optimisation should be considered.
56. A full business case outlining the financial arrangement, the clinical parameters, safeguards to the quality of patient care, patient choice, positive patient outcomes and equality and diversity safeguards will need to be considered
57. Any pilot project or scheme shall require a formal contractual agreement between Provider and Commissioner and will be subject to CRQM and the agreed SUS flex and freeze timetable. Blueteq[®] will be utilised for invoicing purposes.

Medicine Optimisation- In-Patient Services:

58. The Provider shall provide a medication reconciliation service for all elective admissions in accordance with the NICE/ NPSA guidance issued in December 2007.
59. The Provider shall have all necessary systems and procedures in place to maximise the appropriate use of “patients own medicines”. Such procedures should ensure that there is no inappropriate destruction of such medicines.

60. The Provider shall have a policy of supporting self-administration of medication wherever possible and safe to do so in order to maintain patient independence.
61. The Provider must have robust policies around the administration of medicines to patients which adopt best practice principles to uphold patient safety and minimise any adverse outcome to patients.
62. The Provider shall ensure systems are in place to minimise the number of medicines not administered to patients due to the unavailability of those medicines at the required time of administration.
63. The Provider should comply with the Rapid Response Report NPSA/2010/RRR009: Reducing harm from omitted and delayed medicines in hospital.

Medicines Supplied by the Provider:

64. The Provider will ensure the patient's General Practitioner receives an accurate record of all medication supplied on discharge and details of any medicines stopped during their stay in hospital and the reasons for cessation (discharge summary).
65. Clinic letters sent to GP practices should where necessary advise the GP with regard to the medications he/she is expected to continue prescribing. The clinic letters should also state which medicines have been stopped and the reason why. A Read Code diagnosis should also be clearly linked to initiation or recommendation of any new medicines the Provider wishes the GP to continue prescribing.
66. Discharge summaries and clinic letters sent to GP practices should also advise the GP which medications if any, will be prescribed by the specialist, to allow an accurate record to be kept.
67. The Provider shall ensure that all patients being discharged from their care have sufficient information to use any medicines supplied by the provider safely and effectively.
68. The Provider shall ensure that medication is reviewed before discharge and any necessary changes made. When a patient is discharged from hospital and ongoing care is required, medicines and appliances shall be labelled appropriately and supplied by the Provider to the patient in such quantity to last either the complete course of treatment when the course of treatment is less than 28 days or no less than 14 days when treatment is ongoing. The cost of all appliances or medicines will be met by the Provider unless under specific agreement with the Commissioner.
69. Where a patient is supplied with a liquid formulation of an antibiotic which expires before the treatment course can be completed, the Provider must have systems in place to allow the patient to pick up the remaining supply to complete the antibiotic course from their pharmacy. Where it is not possible for the patient to return to the Provider pharmacy to pick up the remaining quantity of antibiotic, the Provider must issue a FP10 prescription such that the remaining supply to complete the antibiotic course can be picked up at a community pharmacy. The Provider must not direct patients to obtain outstanding supplies of antibiotics from their GP practice.
70. Where the patient requires dressings the Provider shall at its own cost, supply sufficient dressings to suffice the patient's needs until the patient is visited by the community nursing service.

71. The Provider shall dispense all items in original manufacturers packaging whenever possible with recognition that in some cases alternative arrangements will be required to ensure compliance with the Disability Discrimination Act (DDA) 2010.
72. Following a DDA assessment of a patient returning to their own home and where the Provider deems a MDS is necessary, they shall provide no less than a 14 day blister supply.
73. The provider will not be required to issue discharge medication for a resident of a Care Home in a MDS. Refer to section 68 for details.
74. When a patient attends a “day-clinic” or out-patient appointment the Provider shall supply at their own cost sufficient dressings as may be needed during a post-operative period, or to suffice until the patient is due to be visited by the community nursing service.
75. When a patient attends a “day-clinic” or out-patient appointment the Provider shall prescribe and supply, at the cost of the Provider a minimum of 14 days supply of any new medication that in the view of the attending clinician is required urgently. Urgent medication is defined as any medication that is required to be started within 2 working days. Non working days are defined as Saturday, Sunday and Bank Holidays. Patients must be informed that the outpatient prescriptions can only be dispensed at the pharmacy located on the hospital site.
76. Patients attending out-patient clinics who do not require medicines urgently (see above), should be advised that the medication is not needed urgently and that the Provider will write to the patient’s GP.
77. The Provider will have systems and processes in place to charge and collect prescription fees from patients who are not exempt to prescription charges. Collection of prescription charges will only apply to dispensed medicines for patients seen in an outpatient clinic setting.
78. The Provider will inform the GP using the approved written form of communication as agreed with the Commissioner, any new medicines which although not classed as urgent, need to be started prior to the GP receiving the standard clinic letter. Similarly, this written form of communication may also be used to inform the GP to stop certain medicines in advance of the GP receiving the standard clinic letter.
79. The Provider shall make the patient aware that it will take the GP at least 2 working days to issue prescriptions for any new medicines from the time the patient presents the request at the surgery.

Patient and Drug Safety Alerts and Error Reporting:

80. The Provider must have systems to receive and comply with alerts regarding medicines from the Chief Medical Officer, Chief Pharmaceutical Officer, MHRA Drug Alerts and MHRA Drug Safety Updates. The Provider must provide evidence with regards to implementation of such alerts if asked to do so by the Commissioner.
81. The Provider shall have a documented process for assessing and acting upon patient safety alerts issued by NRLS and for implementing any recommendations made.
82. The Provider shall provide via its participation and representation at the Area Prescribing Committee details of the Providers response to any relevant patient safety alert.

83. The Provider shall via its Medicines Optimisation Committee or equivalent produce a periodic report summarising incidents and near-misses relating to medicines usage within the Trust. (This may be part of a wider report).
84. The Provider shall report (as an incident) to the Commissioners (Quality Department) any medication errors noted on admission, where such errors may have contributed to the admission or attendance. (This relates to GP prescribing errors which may have resulted in patient harm).
85. The Provider shall support the Commissioners (Quality Department) to review any Datix reported medication errors originating from the Provider.

Clinical Trials:

86. Patients recruited into clinical trials for drugs must receive a full explanation of the nature of the trial, and fully understand that there is no commitment on the part of the Commissioner to fund ongoing treatment at the end of the trial. The Provider shall ensure that patients should understand that this is irrespective of any significant benefit that may be gained from the trial treatment.
87. In cases where treatment cannot be stopped at the end of the trial, exit arrangements and ongoing funding arrangements must be agreed with the Commissioner prior to commencement of the trial.
88. The funding by the CCG of additional costs associated with clinical trials will be in accordance with the NHS Commissioning Board policy statements:

<http://www.england.nhs.uk/wp-content/uploads/2013/04/cp-07.pdf>

<http://www.england.nhs.uk/wp-content/uploads/2013/04/cp-08.pdf>

Private Patients:

89. The Commissioner shall not fund the treatment of patients with any medicines that it would not normally commission. In circumstances whereby a patient can no longer afford or opts out of private care, the patient will be entitled to the same level of care as other NHS Patients.
90. The Provider's clinicians have some responsibility to ensure that private patients are in a position to fund the full course of private treatment.

Specific Commissioning Statement Relating to Medicines Usage:

91. The Provider may request prior approval for funding of treatments through the Individual Funding Request Process.
92. The Provider will abide by any commissioning policies or positioning statements approved by the Commissioner.
93. The Provider will attain at least the minimum standard for each agreed Key Performance Indicators

Equality Impact Assessment

Name of Policy	Commissioning for Quality in Medicines Optimisation
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Aims of policy	The purpose of this policy is to provide clarity on the commissioning intentions of North Staffordshire CCG and Stoke-on-Trent CCG in respect to the quality of medicines optimisation services.
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Does or could the policy have any impact on any of the equality strands in relation to:	Yes	No
<ul style="list-style-type: none"> • Promoting and achieving equality • Eliminating discrimination 		
Ethnicity		N
Religion or belief		N
Disability		N
Gender		N
Sexual orientation		N
Age		N

Give details of how the policy targets or excludes particular equality groups	
Equality area	Reason
Ethnicity	Not applicable
Religion or belief	Not applicable
Disability	Not applicable
Age	Not applicable
Gender	Not applicable
Sexual orientation	Not applicable
Does the policy affect any of the equality groups disproportionately?	No
Are there barriers which could	No

inhibit access to the benefits of the policy? E.g. <ul style="list-style-type: none"> • Communication/ information • Physical access • Location • Sensitivity 	
Does the policy give different groups the same choices as everyone else?	Yes

Indicate what evidence has been used to inform the policy?	
Demographic data and other statistics	N
Recent research findings	N
Results of recent consultations and surveys	N
Results of ethnic monitoring data and any equalities data from local authority /joint services	N
Information from groups /agencies	N
Comparisons between similar functions and strategies	N
PALs complaints and public enquires information	Y
Audit reports and reviews	N
Give details of evidence used to inform the policy	
The evidence used to inform this policy consists of: <ul style="list-style-type: none"> • Advice and guidance from DH • Current relevant regional policies and guidance • NHS England commissioning policies 	
How will the impact of the policy and the impact on different equality groups be monitored?	
Through KPIS Through Datix	

Summary of overall assessment
In summary, any negative impact on equality is unlikely and the policy is concordant with current advice and guidance from DH and NHS England.