Surrey Heartlands Interface Prescribing Policy 2021-22

Version	4.0
Owner	Sarah Watkin, Associate Director of Pharmaceutical Commissioning, Surrey Downs CCG
Committee name	Surrey Heartlands Integrated Care System Area Prescribing Committee
Committee date	7th July 2021
Next review date	March 2022

Organisations ratified	Ashford and St Peter's NHS Foundation Trust Epsom and St Helier University Hospitals Royal Surrey NHS Foundation Trust Surrey and Borders Partnership NHS Foundation Trust Surrey and Sussex Healthcare NHS Trust Surrey Heartlands Clinical Commissioning Group

Adaption required	**Section 5 & 6** to be completed locally in line with agreed arrangements for number of days supply of discharge medicines. CCGs must be assured that providers have systems in place to communicate information required for continued prescribing within the timeframe agreed – usually 7 or 14 days

With acknowledgement to South West London Interface Prescribing Policy 2016-17
Agreed at Prescribing Clinical Network (PCN) meeting: November 2016
Date extension agreed by Surrey Heartlands Integrated Care System Area Prescribing Committee: 7th July 2021

Significant changes since last version			
Version	**Status**	**Who**	**Changes**
2.0	Final	Sarah Watkin, Associate Director of Pharmaceutical Commissioning	Policy is an update of Surrey IPP 2017-19. Changes made after consultation with cross-sector working group and discussions at Surrey and North West Sussex Area Prescribing Committee (formerly Prescribing Clinical Network)
2.1	Draft update	Sarah Watkin, Associate Director of Pharmaceutical Commissioning	Changes made in response to comments from consultation with CCG prescribing leads, CCG pharmacy leads and acute trust Chief Pharmacists: i) TCAM in section 5.4 (NEW) ii) Working with pharmaceutical industry in section 2.15 (NEW) including free samples and added value iii) Updated links: RMOC advice on free of charge medicines; NHSE guidance on items not for routine prescribing; costs for R&D iii) Annex A – removal of drug list from section 3.6. Will add link to PAD iv)Annex A – section 13.2 (d) amended v) Annex A – adalimumab section updated to reflect ned to review when new/revised contract known
2.2	Draft update	Sarah Watkin, Associate Director of Pharmaceutical Commissioning	Changes made in response to comments from APC consultation: i) updated link in section 7.5 ii) Over the counter products in section 7.6 (NEW) iii) Addition of NHSE guidance on conflicts of interest – section 2.15 iv) Annex A – section 13.7 amended
2.3	Draft update	Sarah Watkin, Associate Director of Pharmaceutical Commissioning	Wording amended in response to APC: i) incorporate caveat on working to agree principles for drug charges in section 3.3 and in Annex A section 5 ii) Clarify wording in TCAM – section 5.4 iii) Amend PCN to APC – section 13.2 iv) Annex A – incorporate caveat on working to agree Homecare arrangements in section 7.2

3.0	Final	Sarah Watkin, Associate Director of Pharmaceutical Commissioning	i) Final clarification of TCAM – section 5.4
4.0	Final	Sarah Watkin, Associate Director of Pharmaceutical Commissioning	i) Date extended to March 2022 due to impact of Covid on NHS contracts and funding mechanisms ii) Updated wording re: Surrey Heartlands as a CCG and ICS

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Appendix to the National Standard NHS Contract

1 Introduction

The Department of Health requires that NHS providers establish, document and maintain an effective system to ensure that medicines are handled in a safe and secure manner.

This policy has been produced for providers of NHS services commissioned to deliver services which include prescribing and drugs.

The aim is to facilitate consistent prescribing policies in the National Standard NHS Contracts across Surrey.

It is recommended that Acute Trusts, Mental Health Trusts, Community Services, other relevant providers and Clinical Commissioning Group (CCG) contract managers seek the advice of their Chief Pharmacist/Pharmaceutical Adviser during the commissioning process and discussions to ensure that implications for pharmacy and prescribing are taken into account.

CCGs and providers to which this policy applies will jointly monitor compliance with this policy through regular review via their routine interface and contracting mechanisms.

Hospital Trusts, Mental Health Trusts, Community Services providers, and other relevant providers to which this policy applies are hereafter referred to as “providers”.

2 General Principles

The following general principles will be included in all contracts:

2.1 The provider will adhere to both legal and good practice guidance on prescribing in line with the Medicines Act and any other national/local guidance including shared care. All medicines will be prescribed, handled, maintained, stored, administered and disposed of in accordance with relevant legislation and best practice.

2.2 Providers will have a Drug and Therapeutics Committee (DTC) (or equivalent) in place to co-ordinate the use of medicines, dressings, appliances, enteral feeds and oral nutritional supplements, glucose monitoring strips and any other items that are issued on prescription in a similar way to medicines, across the primary and secondary care interface. The DTC will develop an up-to-date formulary (or equivalent) with the involvement of primary care prescribers and the CCG Pharmaceutical Commissioning / Medicines Management Team.

2.3 Processes for the DTC and any local formulary will be in line with the recommendations in NICE MPG1: Developing and updating local formularies,

and Innovation Health and Wealth: Accelerating Adoption and Diffusion in the NHS.

2.4 Provider prescribing will be from the provider formulary (or equivalent) and prescribers will not seek to avoid formulary restrictions by asking GPs to prescribe non-formulary medicines. Primary care prescribers may wish to highlight any such request to CCG Medicines Management Team and/or provider Chief Pharmacist to identify any themes or specific risks.

2.5 Providers will contribute to the local arrangements for the managed entry of new medicines via the Surrey Heartlands ICS Area Prescribing Committee (APC). This will consider the clinical and cost-effectiveness of new medicines and the impact on primary as well as secondary care. The introduction of new medicines or prescribable* items which have an impact on primary care will be agreed via the APC and ratified by the CCGs unless an alternative local arrangement is explicitly agreed by the CCGs.

2.6 The provider will be responsible for the dissemination and implementation of the recommendations made by the APC via the DTC or equivalent appropriate committee (for other prescribable items*).

**Prescribable items include but are not limited to enteral feeds and oral nutritional supplements, dressings, catheters, stoma items, blood glucose monitoring strips and other items that are issued on a prescription in a similar way to medicines.*

2.7 CCGs will not routinely commission for use, a medicine under review by NICE, for which no appraisal or guideline has yet been published, regardless of the existence of a zero-cost scheme unless there is a local written agreement in place. Any provider signing up to such an offer does so at their own risk and should follow advice issued by the Regional Medicines Optimisation Committee (January 2020). Providers should understand that where the final published guidance does not recommend the therapy, or where the individual patient does not meet the NICE recommended criteria for use, the CCG would in no way be bound to fund on-going treatment.

2.8 Where a medicine receives a positive appraisal and recommendation for use by NICE, local procedures for adoption of NICE recommended medicines will be followed.
Evidence of NICE guidance implementation will be publicised on the provider organisation's website and evidence of compliance may be requested.

2.9 Providers will provide assurance that the recommendations made by the APC are implemented within 3 months. If there are exceptional circumstances when a recommendation is not implemented this needs to be stated. Providers will consider making drugs classified as 'Black' on the Surrey Prescribing Advisory Database (PAD) or local CCG formulary as non-formulary on their provider formulary.

2.10 Prescribers and pharmacists will prescribe and/or recommend, dispense and label by generic drug name except where this is clinically inappropriate or locally agreed.

2.11 Providers will routinely dispense medicines in patient packs, in order to comply with European Community directive 2001/83/EC and Human Medicines Regulations 2012 on pharmaceutical labelling and the provision of information to patients. Where patient packs are not clinically appropriate, providers will make alternative arrangements to ensure patients receive such information. For biologic therapies, providers must issue a biologic alert card and other appropriate support materials to all patients treated with a biologic medicine.

2.12 Providers will have policies in place and approved by their DTC (or equivalent) to cover the safe and secure handling of medicines in line with Royal Pharmaceutical Society Professional Standards for Hospital Pharmacy Services to meet CQC requirements.

2.13 Providers will comply with principles contained in local, national and professional guidance including National Service Frameworks (NSFs), NICE Technology Appraisal Guidance and relevant Health Service Circulars (HSC), NHS Executive Letters (NHS EL) Health and Safety Guidance (HSG) and Audit Commission reports. In particular, prescribing responsibility between primary and secondary care clinicians will be based on the NHS England guidance:-"Responsibility for prescribing between primary & secondary/tertiary care" (version 1, January 2018; publications gateway reference: 07573).

2.14 Legal responsibility for prescribing lies with the health care professional who signs the prescription, and it is the responsibility of the individual prescriber to prescribe within their own competence. For further information see the General Medical Council's 'Good practice in prescribing and managing medicines and devices (2013)'.

2.15 Providers will comply with guidance on managing conflicts of interest issued by NHS England available at: https://www.england.nhs.uk/ourwork/coi/. Providers will adhere to CCG policies for working with the commercial organisations including pharmaceutical industry. Providers will not start patients on free samples of prescribable items unless approved by APC (or local joint formulary). 'Added value' offers or benefits in kind e.g. company sponsored staffing must be explicitly noted in any new drug application and approved by commissioners.

2.16 If a primary care prescriber agrees to take responsibility for continuing to supply drugs which are not normally available in the community, there will be liaison between the transferring provider pharmacy and the community pharmacy to ensure a continuity of supply of the drug.

2.17 Providers will be expected to prescribe and supply in a manner that minimises the potential for waste.

2.17 Providers are expected to implement the recommendations of NHS Patient Safety Alerts and other drug alerts within the time frames specified within the alerts and participate in any relevant audits

2.19 Providers wishing to prescribe any CCG-commissioned drugs excluded from National Tariff must adhere to the individual CCG's 'Arrangements for medicines excluded from the national tariff payment system' document (see Section 3 for information on funding) or a specific locally agreed service**.**

3 Funding

3.1 All new and existing drugs and technologies will be provided within the scope of National Tariff guidance unless:

- explicitly excluded from tariff as described by NHS Improvement in its Drugs excluded from National Tariff list **and** funding is agreed with commissioners, or
- as part of excluded services or
- through local arrangements agreed with the commissioners

Drugs and devices excluded from the National Tariff will either be:

- Commissioned by NHS England; or
- Commissioned by Clinical Commissioning groups (CCGs)

The CCG commissioned drugs and devices will be stated in the individual CCG's 'Arrangements for medicines excluded from national tariff payment system' document (annex A).

Positive NICE Technology Appraisals for PbR excluded drugs will be funded in-year, for providers who can demonstrate competence and compliance with NICE pathways. The APC may identify the local pathways within which the positive NICE TAs may be incorporated.

A full data set as defined by NHS England Clinical Data Set will be submitted for all drug charges and any subsequent challenges. The NHS Clinical Data Sets define the standard information requirements but as a minimum this will include:

- NHS number
- Drug or device name - both generic and brand (statement of brand name for biosimilar products as recommended as good practice by MHRA)
- Quantity supplied e.g. 4 x 50mg prefilled injection
- Date of issue
- Acquisition cost (or reference price if applicable) of drug (CCG can request invoice for verification)
- Speciality or clinical department
- Indication (preferred but not mandatory if speciality or clinical department already stated)

Any additional pre-agreed charges will be listed on a separate line to the related drug or device within the invoice.

3.2 The provider must give confirmation that the patient (or in the case of a minor or vulnerable adult, with the parent/legal guardian/carer) has given appropriate explicit consent for relevant personal, confidential, and sensitive information to be passed to the CCG for processing any new funding or continuation of funding request and for validating subsequent invoices.

3.3 Drug charges must be for the drug only and at acquisition cost or at nationally/locally procured/contracted prices, whichever is lower. There will be no additional charges automatically added to drug prices without prior discussion and explicit agreement with commissioners and in accordance with National Tariff rules. Commissioners and providers will agree principles for funding drugs at cost above contract price as a priority in 2021/22.

3.4 It is the responsibility of the provider to ensure that all national and locally agreed Patient Access Schemes (PAS) are put in place within the provider and all such drugs will be charged to the commissioners as per the detail of the PAS.

The provider will respond to invoice challenges within the contractual time frame for all challenges as agreed.

3.5 Where separate arrangements have been agreed (see the individual CCG's 'Drugs and Devices excluded from the National Tariff' document), CCGs will agree specific funding mechanisms and treatment pathways, for excluded drugs, with providers. Unless otherwise stated, funding for positive NICE technology appraisals is included in the tariff.

3.6 Locally agreed (previously known as pass-through) payments are additional payments for use of a particular device, technology or drug and can be made to providers over and above the relevant tariff reimbursement. CCGs and providers must agree that payment is intended primarily for new devices, drugs, treatments or technologies or to new applications of existing technology. For any locally agreed payment arrangement the following criteria and conditions apply:

- The arrangement will be fixed for a maximum of 3 years
- CCGs will have regard to the existing cost effectiveness evidence including any NICE guidance or other relevant national guidance
- The price attached to the additional funding will be agreed in advance and the price will only relate to the additional costs associated directly with the device or technology and its use relative to the cost of the alternative treatment
- Where additional funding for a more expensive treatment has been agreed on the basis that other costs to the health economy will be reduced, providers will be able to demonstrate that the projected benefits have been realised. Data collection criteria for this will be agreed in advance.

3.7 Exclusions to the contract may be subject to specific reporting requirements which will be agreed in advance.

3.8 Unpredicted in-year cost pressures, excluding NICE technology appraisals, will be managed by discussion between the provider and the commissioners, and will be clearly communicated to all commissioners in advance. A process is in place for considering funding for individual patients on an exceptional basis**.**

3.9 Cost pressures identified as a result of horizon-scanning, including NICE technology appraisals, will be managed by discussion between the provider and the commissioners, and will be clearly communicated to all commissioners in advance.

4 Referrals and admissions

4.1 The referral for specialist assessment must include as per Professional Records Standards Body:

- Medication names, form, strength, dose, frequency and indication for:
  - Acute prescriptions in the last 12 months
  - Repeat prescriptions
  - Discontinued medicines related to referral condition
  - Medicines prescribed elsewhere
- Any adverse reactions or allergies with details of causative agent

Any special supply arrangements must also be included in referral information.

Electronic record sharing systems will be used to facilitate the transfer of information on medicines where available.

4.2 All providers will have medicines management arrangements in line with national guidance (NICE NG5: Medicines optimisation: the safe and effective use of medicines to enable the best possible outcomes) on medicines reconciliation on admission which will include:

- Provision of information to patients before planned admissions about the arrangements in the providers e.g. for bringing in own medicines, self-administration, use of patients own medicines, dispensing for discharge.
- Arrangements for medicines history taking and pharmacist review of medication.
- Exclusions for day cases

4.3 Primary care prescribers will not be asked to prescribe medicines and other items which are intended to be used/administered in hospital out-patient clinics, day-care surgery (e.g.: intra-uterine levonorgestrol implants, topical anaesthetic creams) or in patient's home if provided as part of a package of care or medicines required as part of a planned procedure (e.g. anticoagulation bridging). Note: this does not apply to those medicines which have been prescribed by the GP for patient's use at home and which the

patient has brought into the provider as a “patients own medicine” for an in-patient stay. It is the provider’s responsibility to ensure that arrangements are in place to ensure any treatments are available as appropriate.

4.4 The requestor of any test is responsible for ensuring any action required as a result of that test. Providers will ensure that any treatment required as a result of pre-operation assessment clinics e.g. MSU and MRSA testing is supplied to the patient by the requestor in a timely manner and for the whole treatment period.

5 In-patients

5.1 CCGs encourage the use of patients own medicines in hospital in line with the Audit Commission report ‘A Spoonful of Sugar’ (2001). GPs and other primary care professionals should encourage patients to take their own medicines with them into hospital. If the patient has brought their own medicines into hospital with them and they are suitable for use, these can be used on the wards in line with the provider’s local policy.

5.2 CCGs and providers encourage the use of “green-bag” and “message in a bottle” schemes.

5.3 The provider is responsible for the supply of any new medicine or continuation of existing medicines to in-patients when the patient’s own supply drops below XX days. This may exclude specified continuing care units.

5.4 Providers will support safe discharge by using digital referral to community pharmacists for identified patients (as agreed with the ICP project team for TCAM). If not yet available, the provider will work towards implementation according to agreed service development improvement plan for 2021/22.

6 Discharge Arrangements

The general principle is that all providers will ensure patients will be discharged with access to XX days, of **all** their medicines (including pre-admission medicines), in line with local policy.

6.1 The provider must supply that quantity of medication to the patient, except to the extent that they are assured that the patient already has an adequate quantity and/or will receive an adequate supply via an **existing repeat prescription** from the patient’s primary care prescriber.

6.2 Patients will normally be discharged from providers **in line with local policy**, with a **minimum supply of XX days** or an original pack, whichever is the higher (including trusts employing dispensing for discharge systems) unless:

- The full course of treatment is less; or
- The patient is palliative when a quantity appropriate to the patient’s need will be supplied; or

- When responsibility for prescribing remains with the hospital (section 13), an adequate supply will be given to ensure continuity until next clinical review; or
- Local arrangements are in place for other prescribable items e.g. enteral feeds supplied according to contract

This also applies to existing pre-admission medicines when the patient's own drug supply is less than XX days on discharge but not if there is a minimum of XX days of patient's own drug supply left.

6.3 The requirement to supply a minimum of XX days of medication on discharge also applies to patients requiring adherence support, including patients requiring multi-compartment compliance aids (see section 6.9 for further details).

6.4 The GP will be provided with the following information about the patient's medicine:

- Diagnosis and reason for admission
- Medicines on discharge (including dose and frequency) with clear instructions as to whether or not the medicine should be continued after the initial supply
- Any monitoring required including anticipated increase/decrease in dose
- For all new medication, the specific reason for starting the new medication will be stated and the duration of treatment will be indicated where appropriate (e.g. clopidogrel, PPIs, antibiotics)
- For any existing medication which is stopped, the specific reason for stopping will be stated.
- For any pre-admission medicine which is changed, the specific reason for the change will be stated
- For any medicines requiring ongoing prescribing by hospital, and initiated on the current admission, arrangements for ongoing supply must be in place and this will be communicated on the discharge summary
- If patients are initiated on enteral feeds or oral nutritional supplements, dressings or appliances (e.g. stoma appliances, catheters), the provider is expected to provide communication from the initiating clinician to the GP regarding the patient's clinical care plan and quantities required for ongoing prescribing/supply.
- Clear instructions on medications (reasons for taking them, dosage, when to take them, and any other additional instructions)
- Details of medicines tried in hospital but which proved unsuitable
- Details of any compliance aids issued e.g. reminder charts
- Any information on allergies in line with NICE CG 183 Drug allergy: diagnosis and management from September 2014

6.5 For patients admitted for a reason unconnected with their previous medication regimen, e.g. for surgery, the discharge information must list any drugs added

and still in use at discharge. If the remaining drugs are unchanged then the discharge notification can state “Other drugs as at pre-admission”.

6.6 For patients admitted for a reason unconnected with their previous medication regimen, e.g. for surgery **and** where there is no change in any medicine at discharge, the discharge information can state “no changes made”.

6.7 Discharge information will be sent to the patient’s GP at the time of discharge. Discharge information will be electronic and sent within 24hrs of patient discharge to the GP and copied to the patient (or sent to the GP within 1 working day in cases where the patient has died).

6.8 Patients will be provided with appropriate information about obtaining further supplies of medicine.

6.9 Patients at risk of experiencing problems managing their medicines should be identified and, if appropriate, a referral made for pharmaceutical support. Any issues identified as a risk to safe discharge will be dealt with internally.

6.10 **Monitored Dosage Systems and other Compliance Aids**
Providers are encouraged to develop discharge planning arrangements for vulnerable patients. The use of monitored dosage systems and other compliance aids are not routinely supported unless clinically required - an assessment for appropriateness will be undertaken in line with the Royal Pharmaceutical Society’s 2013 guidance on better use of multi-compartment compliance aids before a monitored dosage system is initiated. Where the supply of a monitored dosage or other similar system is appropriate there will be a policy in place for its use including making appropriate arrangements for continuity after discharge.

6.11 Dispensing for Discharge (One Stop Dispensing)
Providers are encouraged to employ a dispensing for discharge system in line with the Audit Commission report ‘A Spoonful of Sugar’ 2001.

7 Out-patients/Day Case

7.1 Medication will be provided for outpatients in line with local policy.

In some providers this may include writing to the primary care prescriber and suggesting medicines if **not** required for immediate treatment i.e. initiation not required within 14 days. When recommending treatment, the consultant where possible, will recommend a therapeutic class of drug, rather than a specified product.

Patients will be provided with written information telling them that the medicine is not urgent and that they should contact their surgery in approximately 14 days when the surgery will inform them when to collect their prescription.

Full information will be received by the primary care prescriber to enable a prescription to be issued – the advice letter from the provider will normally be

received within 7 days. Where this is not possible, patients will receive supplies from the provider. Providers will ensure that outpatient letters are completed so that professionals, patients and carers receive timely, consistent, reliable, high quality information between clinicians and patients. For safety and clarity, any changes in medication or route of supply will be highlighted and a clear statement given to indicate if a primary care prescriber is being asked to initiate or change medication, or to highlight any regular medicines that will be supplied from the provider.

7.2 The following categories must be prescribed by the providers:

- Medicines required for immediate treatment (i.e. initiation required within 14 days) e.g. antibiotics
- Drugs agreed with the CCG as provider/specialist only (Red drugs)
- Drugs requiring continued monitoring or where an agreement to shared care is pending (Amber or Amber-star/ Blue Drugs)
- Provider based clinical trials
- Compassionate supply medicines

7.3 Where a prescription is issued the quantity provided will be in line with local policy. Patient packs will normally be dispensed unless the full course of treatment is shorter (e.g. antibiotics, short-term analgesia or short-course corticosteroids). A longer supply may be indicated e.g. where the dispensed pack cannot be easily divided; for diabetics receiving insulin, or when the consultant feels there are clear medical reasons why they will supply the whole course (monitoring requirements) or when ongoing drug treatment is part of a commissioned service (in which case the drug will be included within tariff).

7.4 Providers will ensure that their outpatient prescription form clearly states that the prescription can only be dispensed at the provider's own pharmacy and cannot be taken to any other pharmacy or to the patient's primary care prescriber to request a prescription. Providers must ensure that patients are made aware of this and make provision for supply even if out of stock.

7.5 Primary care prescribers should not be asked to initiate products specified in the NHS England document '*Items which should not routinely be prescribed in primary care: Guidance for CCGs'* unless the patient has exceptional circumstances as identified by the guidance. Similarly, for patients newly initiated on such treatment by the Provider, GPs should not be asked to continue this treatment unless exceptional circumstances apply as per guidance.
For a full list of items and exceptional circumstances, the guidance can be accessed via:
https://www.england.nhs.uk/medicines/items-which-should-not-be-routinely-prescribed/

7.6 Primary care prescribers should not be asked to initiate products specified in the NHS England document *'Conditions for which over the counter items should not routinely be prescribed in primary care: Guidance for CCGs'* unless the patient has exceptional circumstances as identified by the guidance.

Similarly, for patients newly initiated on such treatment by the Provider, GPs should not be asked to continue this treatment unless exceptional circumstances apply as per guidance.
For a full list of items and exceptional circumstances, the guidance can be accessed via: https://www.england.nhs.uk/medicines/conditions-for-which-over-the-counter-items-should-not-routinely-be-prescribed/

7.7 Providers will communicate any ongoing treatment plan for medicines administered by providers on a one-off/infrequent basis e.g. annual dose of intravenous zoledronic acid. Primary care prescribers will ensure that patient medication records include and accurately record these medicines and treatment plan in order to be alert to potential side-effects and interactions with other medicines prescribed in primary care. This will ensure that primary care records, which are accessed by other healthcare providers, are a true and accurate reflection of the patient's medication

8 Homecare

8.1 Providers and commissioners will fully implement their responsibilities as described in Royal Pharmaceutical Society Professional Standards for Homecare Services. Suitable arrangements for setting up homecare services, including the responsibilities of providers and CCGs and funding arrangements will be clearly identified prior to setting up the service.

9 Other prescribable items

9.1 The provider will work with the commissioner when contracts are negotiated for the procurement or supply of items such as continence or stoma devices, glucose monitoring devices or enteral feeds and oral nutritional supplements which may require ongoing prescription in primary care.

9.2 In the case of Oral Nutritional Supplements (ONS) providers will only supply feeds on discharge if accompanied with a nutritional management plan including a Malnutrition Universal Screening Tool (MUST) score completed by a dietician and goals of treatment. Oral nutritional supplements requested on discharge will be reviewed for ongoing need and swapped to cost effective products in line with primary care prescribing guidance unless it is clearly stated in the dietician's letter that the ONS requested is unsuitable for swapping.

9.3 Suitable local arrangements will be in place for the supply of dressings and appliances. A minimum of five days' supply will be provided. Sufficient information about a patient's dressing and appliance treatment will be provided to ensure continuity of care in the community. See also section 6.4 regarding communication with the GP.

9.4 Providers will not request primary care prescribers to prescribe dressings outside of the CCG's dressing formulary.

9.5 No arrangements will be made by the providers with appliance contractors for ongoing supplies of dressings or appliances in the community without involving patients in the decision about where their prescriptions are dispensed.

10 Patients attending Accident and Emergency

10.1 If a prescribed medicine is necessary and the required treatment course is ≤ 14 days, the full course will be supplied. Where longer term medication is required, a minimum of 14 days treatment will be supplied. This is to allow the primary care prescriber sufficient time to receive the information about the patient's A&E attendance and arrange a continuing supply. In all other circumstances, 7 days treatment should be supplied (unless the treatment course is shorter).

10.2 Information will be sent to the GP within 3 working days and will include a minimum data set as specified in section 6.4

11. People at risk of harm

11.1 When making arrangements for the prescribing of medicines for someone who may be at risk of self-harm or have the potential to misuse the medication, the arrangements should fit within the overall care plan for the individual service user. In addition, the safe use of some medicines requires specific information resources; such as the patient guide, prescriber checklist and patient card for girls and women of childbearing age who may be taking or considering taking certain medicines such as valproate.

12. Unlicensed Medicines or medicines used outside of their licensed indication(s) (see also APC's document 'Recommendations to Prescribers on the Use of Unlicensed Medicines and Licensed Medicines for Unlicensed Indications')

12.1 Prescribing of unlicensed medicines or medicines used outside their licensed indications will usually remain the responsibility of the clinician initiating treatment. The provider will accept full responsibility for the continued sourcing, quality and supply, which will be under the control of the provider pharmacy department. In these cases, information must be given to patients explaining that they must obtain continuing supplies of their medicine only from the provider, not their primary care prescriber.

12.2 Where there is a substantial body of evidence to support the use of an unlicensed medicine or a licensed medicine outside of its licence (e.g. in paediatrics), the primary care prescriber may be asked to prescribe. However, they must be fully informed and made aware of the licensing status. The primary care prescriber will refer to the BNF / Children's BNF as a guide for prescribing of unlicensed medicines / licensed medicines outside of licence. The full agreement of the primary care prescriber concerned must be obtained before prescribing is transferred.

12.3 Informed consent for the use of unlicensed medicines or the use of licensed medicines outside their licensed indications will be obtained from patients before the prescription is written.

12.4 Prescribing of products classified as Borderline Substances outside of circumstances approved by the Advisory Committee on Borderline substances (ACBS) remain the responsibility of the clinician initiating treatment. The provider will accept full responsibility for the continued sourcing, quality and supply, which will be under the control of the provider pharmacy department. In these cases, information must be given to patients explaining that they must obtain continuing supplies of their medicine only from the provider, not their primary care prescriber.

13 When Responsibility for Prescribing Remains with Providers Note: this applies to CCG commissioned drugs only, not those commissioned by NHS England Specialised Commissioning.

13.1 The provider trust is expected to retain prescribing responsibility for the following:

- Medicines requiring ongoing specialist intervention and specialist monitoring including those classified as RED and those subject to transfer of care arrangements (AMBER or BLUE medicines with minimum supply criteria)
- Patients receive the majority of ongoing care, including monitoring, from the provider and the only benefit of transferring care would be to provider costs.
- Medicines that are unlicensed or are being used outside of the product license e.g. for an unlicensed indication or at an unlicensed dose unless there is a recognised evidence base and/or it is standard treatment. In terms of paediatric medicines, inclusion of dosage guidance in the children's BNF provides a suitable evidence base (see section 11.2 for clarification)
- Medicines that are only available through the provider i.e. are not available on FP10 including certain 'borderline' products when used outside approved indications.
- Medicines that are part of a provider initiated clinical trial or the continuance of a provider initiated clinical trial or compassionate use, where no arrangement has been made in advance with the purchaser to meet the extra cost of the treatment.
- The primary care prescriber does not feel confident in taking on clinical responsibility for the prescribing of a drug and there is no shared care guideline for that drug.
- Medicines and other items e.g. dressings which are intended to be used/administered in the provider's outpatient clinics or day-case surgery e.g. intrauterine levonorgestrel implants, local anaesthetic creams.
- Medicines and other prescribable products, which have not been approved for addition to the provider's formulary.
- A medicine under review by NICE, for which no appraisal or guideline has yet been published

- Drugs that have not gone through due consideration processes at the CCG
- All anti-cancer medicines except where shared care prescribing or other arrangements exist.
- All other treatments funded by NHS England unless specifically agreed to be provided through a shared care prescribing agreement or other agreed process
- Where there has been no collaboration or agreement with the patient and/or carer.
- Packages of care:
  - CCG commissioned injectable antibiotics, antifungals and antivirals (unless special local arrangements exist)
  - Drugs for IVF (see local CCG policy)
  - All orphan drugs* commissioned by CCGs
  - Insulin pumps (package of care)

* Orphan drugs are those designated by the EMA to promote development of drugs to treat rare diseases or conditions. They have marketing exclusivity for 10 years with assistance from the EMA in optimising drug development and applications for marketing approval.

13.2 If there is disagreement about where prescribing of an individual patient's treatment should best take place the case will be referred to the CCG, via the Medicines Management team who will seek resolution between the parties concerned. Disagreements over the principles of prescribing responsibility, not individual disagreements that are resolved case by case, are probably best resolved at the Area Prescribing Committee. Care will be taken to ensure that the patient does not suffer as a consequence of the NHS decision-making process and co-operation on both sides is sought in achieving resolution in difficult situations.

13.3 Repeat prescriptions for specialist drugs will not incur an attendance tariff charge unless the patient receives a clinical review. The provider will make arrangements for issuing medication in between clinical reviews as appropriate.

13.4 Primary care prescribers will be informed of any drugs which continue to be prescribed by the specialist. Discharge and outpatient letters will clearly state that these drugs are to be supplied by the provider and that the primary care prescriber is not expected to prescribe.

13.5 Primary care prescribers will ensure that patient medication records include and accurately record any medicines for which prescribing remains the responsibility of secondary or tertiary care providers in order to be alert to potential side-effects and interactions with other medicines prescribed in primary care. This will ensure that primary care records, which are accessed by other healthcare providers, are a true and accurate reflection of the patient's medication.

14 Transfer of Prescribing - Medicines Requiring Specialist Monitoring (drugs that are classified as Amber or Amber*/Blue on the CCG traffic light system)

Increasingly, patients with continuing specialist clinical needs can be cared for at home or in the community. There are medicines which could be prescribed by primary care prescribers if sufficient support, review and information are shared between the primary care prescriber and consultant.

14.1 It is the responsibility of the specialist to request shared care with a primary care prescriber.

The key principle is that the primary care prescriber is provided with information and given the opportunity to accept prescribing responsibility before informing the patient and before the transfer takes place.

Under no circumstance will the patient be used as the mechanism for informing the GP that prescribing will be transferred to them.

14.2 It would not normally be expected that a primary care prescriber would decline to prescribe on the basis of cost unless there is a clinically suitable cost-effective alternative available. Likewise, if the patient is to receive the majority of their on-going care through the provider then prescribing must remain with the provider and must not be transferred solely on the basis of cost or practical considerations of supply.

14.3 The following conditions will be met before shared care takes place:

- The initial specialist responsibilities set out in the shared care guideline have been fulfilled
- Treatment is in accordance with a patient-specific shared care protocol / information leaflet which clearly defines the responsibilities of all parties. This document must have been approved by the Trust DTC and by the CCG Medicines Management Committee (or equivalent) and must contain the trust logo and contact details for the relevant department and clinician in the back-up advice and support section of the document.
- The written agreement of the patient's GP is given prior to the transfer of prescribing.
- The primary care prescriber is sufficiently informed and able to monitor treatment and identify medicines interactions.
- Specialists will ensure that patients are aware of and understand their responsibilities to attend appointments and undertake appropriate monitoring arrangements. They will advise patients that their medicine may be stopped if they do not fulfil these responsibilities.

All prescribers will be aware of their responsibilities to develop their own and the expertise of others in the managed introduction of new medicines.

15 Tertiary Care Referrals

15.1 It is expected that the care and treatment of patients referred to tertiary care will remain the responsibility of the tertiary centre while they continue to require specialist care or as indicated within NHS England service specification.
If NHS England are providing an advisory service for the assessment and development of a treatment plan only, the referrer is responsible for making prescribing decisions in relation to the referral.

Primary care prescribers will only be asked to prescribe drugs initiated by tertiary care referrals if this is compliant with the interface prescribing policy (IPP).

15.2 Where it is clinically appropriate for the patient to be cared for at home, under the supervision of the tertiary centre, the centre will make appropriate arrangements for prescribing and supply of specialist medicines (e.g. 'Purchasing high-tech healthcare at home' EL95/5 or using FP10(HP)s).

15.3 In some circumstances it may be appropriate to transfer prescribing to a more local provider trust or more rarely a primary care prescriber. In all situations there will be robust processes in place between the tertiary centre, provider trust and primary care prescriber to ensure timely and accurate transfer of a patient's medication details to appropriate professionals responsible for the patient's care.

16 Patient Group Directions

16.1 Providers wishing to use Patient Group Directions (PGDs) to deliver any part of the service are required to develop and use PGDs within the appropriate clinical governance framework as outlined in national guidelines (e.g. NICE Good Practice Guidance MPG2) and obtain appropriate medical and pharmaceutical advice in drawing up the documents. Where the legal framework does not allow this, the provider may seek advice from the Commissioner. Providers are reminded that PGDs will not be used to supply unlicensed medicines and in the case of antimicrobial medicines, should comply with national guidelines.

17 Non-Medical Prescribing

17.1 Nurses, pharmacists and other allied health professionals who become qualified prescribers are expected to work within the policies and guidelines of their employing organisation and the established agreed local prescribing guidelines.

17.2 The provider must ensure that non–medical prescribers will:

- Be accountable for, and prescribe within, their own level of competence and expertise
- Seek advice and make appropriate referrals to other professionals with different expertise, when required

- Adhere to the Code of Conduct and Ethics of their regulatory body, ensuring they have sufficient professional indemnity insurance, by means of membership of a professional organisation or trade union which provides this cover
- Ensure competencies are maintained through continuous professional development and clinical supervision.

18 Clinical Trials & Ethics Committees

18.1 All clinical trials must have been subject to Research Ethics Committee approval, when the arrangements for consulting and informing will be considered. Trials should also have been through the Provider Trust's Research Governance process. This will take account of whether or not the trial is in line with strategic objectives of the organisation (for research and clinical care) and continued supply of medicines at the end of the trial.

From 31 March 2016, Health Research Authority (HRA) Approval is the process for applying for approvals for all project-based research in the NHS led from England. Therefore, all project-based research is subject to approval from HRA Approval.

18.2 In order to respond appropriately to any suspected adverse events that occur outside the provider setting, following patient consent, the primary care prescriber will be adequately informed if a patient is participating in a clinical trial.

18.3 Prescribing and supply of clinical trial medicine is the responsibility of the provider. Costs (including Excess Treatment Costs) will be attributed in line with latest national guidance (AcoRD). Standard out-patient or in-patient treatment costs will be met for patients on a trial as required by HSG(97)32; this will not include the cost of the trial medicines either during or after the trial unless specifically agreed with the relevant commissioner.

18.4 Patients participating in a clinical trial must be made aware that there is no guarantee that the medicine will be continued at the end of the trial, irrespective of the results. Where trial results indicate that treatment will continue, post-trial costs will only be considered for funding by CCGs where exceptional circumstances exist.

18.5 Primary care prescribers should be aware that their patient is receiving a "hospital only clinical trial medicine" and ensure that this is recorded in the patient's notes in order to be alert to potential side-effects and interactions with other medicines prescribed in primary care. This will ensure that primary care records, which are accessed by other healthcare providers, are a true and accurate reflection of the patient's medication.