

## Coastal West Sussex Interface Prescribing Policy

Agreement between  
Commissioners: Coastal West Sussex Clinical Commissioning Group (CWS  
CCG)

And

Providers: Western Sussex NHS Foundation Trust (WSfT)  
Sussex Community NHS Foundation Trust (SCfT)  
Sussex Partnership NHS Foundation Trust (SPfT)  
All Other Commissioned Providers

This agreement has been approved by: CWS Area Prescribing Committee (APC)

Initial production date: February 2016

Revision date: September 2019

Date of next review: September 2021 or sooner in light of new national guidance

Originally adapted from the South West London Interface Prescribing Policy (including subsequent revisions)

# Coastal West Sussex Interface Prescribing Policy

## **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 by Coastal West Sussex Clinical Commissioning Group (adapted from the South West London Interface Prescribing Policy) as best practice and is to be agreed by Acute, Mental Health, Community Services Providers and Clinical Commissioning Groups (CCG's), Drug and Therapeutics/ Medicines Optimisation/ Prescribing Committees within the Coastal West Sussex area. It is however recognised that on occasions a specific element/s of this policy may be superseded by recommendations or guidance provided by Regional Medicines Optimisation Committees (RMOCs).

It outlines the contractual requirements for licensed providers of NHS services and aims to avoid confusion about where prescribing responsibilities sit between care settings by defining the prescribing arrangements between the commissioners (Coastal West Sussex CCG) and providers (Western Sussex Hospitals NHS Foundation Trust (WSHfT), Sussex Community NHS Foundation Trust (SCfT), Sussex Partnership NHS Foundation Trust (SPfT) and all other specialist commissioned providers including palliative, dental and urgent care providers.

Providers are expected to put systems in place to ensure that this Interface Prescribing Policy is highlighted and adhered to by all clinicians and other healthcare staff and are required to provide assurances of such to the CCG. This includes measures to ensure that the policy is brought to the attention of existing and new staff and that breaches are addressed within clinically appropriate timescales.

It is recommended that Acute Trusts, Mental Health Trusts, Community Services Providers, other relevant providers and CCG contract managers seek the advice of their respective Chief Pharmacist or Pharmaceutical Advisers during the commissioning process and Commissioning Strategy/Operating Plan discussions to ensure that implications for pharmacy and prescribing are taken into account.

## **2. Aims of This Agreement**

- 2.1 To promote the quality of patient care through rational, evidence based, cost effective prescribing in the Coastal West Sussex area that promotes consistency, best practice and value consensus across the primary/ secondary care interface.
- 2.2 To define the principles for prescribing and supply of medication on transfer following outpatient attendances to ensure that patients are never placed in a position where they are unable to obtain the medicines that are required.

- 2.3 To better inform prescribers as to their responsibilities and the expectations of providers and commissioners alike.
- 2.4 To define prescribing arrangements locally.
- 2.5 Coastal West Sussex CCG require that the prescribing and medicines management service provided by WSHfT, SCfT, SPfT and other commissioned providers comply with service specifications.
- 2.6 The CCG and Providers should jointly monitor compliance with this policy, initially raising any concerns internally between department/ service managers escalating only to the CWS Area Prescribing Committee where resolution of ongoing lack of compliance cannot be resolved.

### **3. General Principles**

- 3.1 Prescribing across the health economy will be in line with the [Coastal West Sussex Local Health Economy Formulary](#), all prescribers within CWS have a responsibility to be aware of the formulary and the medicines contained within it, which are identified through the traffic light system.
- 3.2 Prescribers and pharmacists will prescribe/ recommend, dispense and label by generic name except where this is clinically inappropriate to prescribe by brand or agreed through the CWS Area Prescribing Committee.
- 3.3 Medicines are routinely dispensed in patient packs, in order to comply with European Community directive 92/97EEC on pharmaceutical labelling and the provision of information to patients. Where patient packs are not clinically appropriate (e.g. continuing dose adjustment, risk of self-harm, monitored dosage systems) providers must make alternative arrangements to ensure patients receive such information.

#### **Providers (organisational) must ensure that:**

- 3.4 There is a Medicines Optimisation Committee (or equivalent) in place to triage and coordinate the use of medicines, appliances, dressings and other prescribable items, prior to submission to the CWS Area Prescribing Committee.
- 3.5 Discretion be exercised when considering purchasing agreements; considering cost effectiveness for primary care where continued prescribing will be in within general practice.
- 3.6 Prescribers will not seek to avoid restrictions by asking GP's to prescribe non-formulary medicines; nor will prescribers within provider organisations use FP10 prescriptions as a route to prescribe non-formulary drugs; any requests for non-formulary medicines should follow the local provider's policy and process and may be subject to compliance monitoring. However it is recognised that within SPfT, there may be exceptional circumstances whereby such supply mechanisms may exist solely on an agreed named patient basis. Specialists within the relevant field will contribute, by way of providing clinical expertise in the application for new medicines and presentation of said application to the Coastal West Sussex Area Prescribing Committee enabling the provision of further information regarding the application at the time of consideration in advance of the committee reaching a decision. This should consider the clinical and cost-effectiveness of new medicines, the

impact on primary and secondary care and all related issues including delivery of care, commissioning and procurement arrangements.

3.7 Through its governance processes, locally agreed formularies and guidelines are adhered to by all prescribers and healthcare professionals involved in the care of patients provided (on behalf of) the provider. Exceptions may exist when patients are admitted on established non-formulary medicines.

3.8 Up-to-date policies are in place, approved by their Medicines Optimisation Committee or equivalent which should cover :

- Medicines Management including the use and disposal of patients own medicines in hospital or other care settings
- Use of unlicensed medicines and medicines used for unlicensed indications
- Working with the pharmaceutical industry
- Non-medical prescribing
- Development and implementation of Shared Care Agreements
- Development and implementation of Patient Group Directions (PGDs)
- Private patient care: NHS patients who wish to pay for additional private care
- Homecare

Evidence for the above standards may be requested by the commissioner.

3.9 Specifications should reflect principles contained in local, national and professional guidance, including the National Service Frameworks (NSFs), NICE Technology Appraisal Guidance and relevant Health Service Circulars (HSC), NHS Executive Letters and Health and Safety Guidance (HSG) and Audit Commission reports. In particular prescribing responsibility between primary care prescribers (GP's, Advance Nurse Practitioners, Clinical Nurse Specialists, Clinical Pharmacists holding an independent prescribing qualification) and secondary care clinicians should be based on NHS England guidance (gateway ref. 07573).

3.10 Systems of communication will consider the patient as central and will maximise the benefits to patients. Consideration should be given to patients wishing to have greater involvement in the information and decisions about their medicines. However patients should not be required to be the communication method between parties. Robust, reliable and secure communication mechanisms exist to ensure information about a patient's medication and proposed treatment plan is available to appropriate healthcare professionals responsible for their care including patients and their carers in a timely manner.

3.11 Evidence of compliance with NICE guidance may be requested e.g. via an agreed work plan.

3.12 Principles of antimicrobial stewardship are considered when discussing the use of antibiotics with a patient, this is to ensure consistency in messages provided to patients in addition to when selecting an antimicrobial for prescribing, in particular where the patient may have already seen and treated/ assessed as not requiring treatment by a primary care clinician before presenting.

- 3.13 Recommendations of NHS Patient Safety Alerts and other drug alerts are implemented within in the desired timeframe stipulated which the individual alert, ensuring appropriate communication to patients and primary care prescribers where required.
- 3.14 Prescribing responsibilities and decisions reflect the seven elements of Medicines Optimisation:
- Patient experience
  - Evidence based
  - Making medicines optimisation routine practice
  - Safety
  - Patient outcomes
  - Patient centred
  - Measurement and monitoring
- 3.15 Where applicable, recommendations from within the Carter Reports are implemented to further support Medicines Optimisation, aiding the delivery of improved patient outcomes across the health economy

#### **4. Funding**

All NHS drugs prescribed will either be:

- Commissioned by the Specialised Commissioning Group (SCG) which is part of NHS England OR
- Commissioned by Clinical Commissioning Groups (CCGs).

(This section relates to drugs commissioned by CCGs only.)

- 4.1 All medicines are normally included in the national standard contracts unless they are specifically excluded from Tariffs (CWS Commissioning Principles for High Cost Drugs and Devices excluded from Tariff, further detail of this are available from High Cost Drugs leads within respective organisations). For CCG commissioned drugs, the CCG will agree specific funding mechanisms for excluded drugs assigned to CCGs with Providers. Unless otherwise stated funding for NICE technology appraisals is included in the Tariff.
- 4.2 Exclusions to the contract may be subject to specific reporting requirements.
- 4.3 Cost pressures or cost savings identified as a result of horizon-scanning, including NICE technology appraisals, will be managed between the provider and commissioners and will clearly be communicated between affected parties in advance of yearly contract negotiation.
- 4.4 Unforeseen in-year cost pressures, excluding NICE technology appraisals, will be managed by discussion between the provider and commissioner and will be clearly communicated in advance. A process is in place for considering funding for patients on the basis of an individual funding request (IFR).
- 4.5 Inflationary uplifts identified by commissioners for prescribing or NICE TAG implementation should be realised in the commissioner's and providers' prescribing budgets.

## 5. Primary care arranged admissions

### Primary care prescribers must ensure that:

5.1 A referral letter will be sent at or before admission taking account of recommendations made in [NICE Guideline 5](#) and should cover relevant information appropriate to the individual patient which may include:

- Medicine history
- Current medicines – drug, form, strength, dose frequency and indication Including those recommended for self-care or identified as currently being purchased over the counter and those to be prescribed by secondary care (also to include length of treatment if applicable)
- ‘Last dose’ information, where medicines are administered weekly, monthly, quarterly - when the last dose was taken/ administered
- Where medicines require specific monitoring - when monitoring was last undertaken/ is next due
- Relevant compliance issues (dexterity, visual impairment, compliance aid requirements )
- Previous adverse reactions and allergies (including type and severity of reaction)
- Any significant medical history
- Reason for referral/ suspected diagnosis.

### Secondary care providers will ensure that:

5.2 Medicines management arrangements on admission are in place and include:

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

## 6. Inpatients

6.1 The CCG encourages 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 healthcare professionals should encourage patients to take their own medicines with them into hospital. Ambulance service providers are encouraged to be aware of this practice and to assist in facilitating for emergency admissions. 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.

**Secondary care prescribers must ensure that:**

- 6.2 The supply of any new medicines or continuation of existing medicines to in-patients is made, when the patient's own supply drops below 7 days, unless the patient has sufficient supply at home.

**7. Discharge / Transfer**

**Secondary care prescribers must ensure that:**

- 7.1 A holistic approach will be taken when considering the selection of medication intended for ongoing primary care prescribing, in addition to delivery/administration method. The patient's adherence, quality of life and engagement in the proposed therapy must be balanced against the immediate and longer-term impact on both the GPs and secondary care clinicians staffing and financial resources. They will not seek to avoid restrictions by asking GP's to prescribe non-formulary medicines; nor use FP10 prescriptions as a route to prescribe non-formulary drugs
- 7.2 When supplying medication to patients on discharge or recommending medications for primary care to supply, providers must have regard to national guidance published by NHS England on [over the counter medicines](#) and [items that should not be routinely prescribed](#).
- 7.3 At the point of discharge/ transfer following an inpatient stay, patients should be discharged/ transferred from the hospital:
- For existing medications where no changes have occurred, with a minimum supply of 7 days (taking into account bank holidays and weekends).
  - For existing medications where no changes have occurred and the patient has more supply at home, with enough supply in total to 7 days (taking into account bank holidays and weekends).
  - For patients using monitored dosage systems (MDS) where a medication change has occurred, a supply of 7 days in a MDS (SPfT may provide the patient with FP10 prescription to be dispensed under their regular pharmacy arrangements).
  - For a newly initiated medication, an original pack unless the full course of treatment is less or the patient is palliative when a quantity appropriate to the patient's need should be supplied (this also applies to out of hours, at weekends and on bank holidays).

However exceptions may exist where:

- Smaller quantities may sometimes be used where the overall risk to the patient outweigh the benefits e.g. where there is a risk of overdose or the potential of misuse and or diversion; the decision to provide a shorter supply duration should fit within the overall care plan for the individual and the appropriate patient and prescriber resources.

- The reason for the supply of smaller quantities, a care plan for how long this will last or information on a review date should be communicated with clear instructions on how many days should be prescribed.
  - Larger quantities may be provided on a discretionary basis e.g. where a full course of treatment may be indicated for a defined duration only or when the specialist feels there are clear medical reasons for supplying the whole course (monitoring requirements).
- 7.4 When patients are discharged/ transferred from hospital after a 48 hour or less stay they will be provided with a minimum of 7 day's supply of any medicine that has been initiated during their stay. Supplies of existing regular medication will not be routinely provided unless the patient does not have any supplies at home. This will mean:
- Reduction of risks by avoiding confusion to patients who may be issued with further supplies of their regular medication but in different packaging or brand to what they are used to
  - Reduction in the length of stay through avoidance of waiting for transfer medication
  - Reduction of waste from unused medicines
- 7.5 Patients admitted for less than 48 hours where there is no change in any medication at discharge/ transfer, discharge information is to explicitly state no change to regular medication.
- 7.6 GPs receive a transfer summary within 24 hours of discharge. Transfer information should be electronic where available or must be legible and include the following details:
- Notification of diagnosis and reason for admission
  - Changes to medication (including reason) prescribed before admission
  - Medicine on discharge/ transfer, name, strength, form, dose, frequency / timing, duration in addition to indicating whether the medicine should be continued after the initial supply (see 7.2 and 7.3)
  - For all new medication, the duration of treatment should be indicated where appropriate (e.g. clopidogrel, ticagrelor, PPI's, antibiotics)
  - Last dose' information, where medicines are administered weekly, monthly, quarterly; when the last dose was taken/ administered
  - Newly identified adverse reactions and allergies (including type and severity of reaction)
  - For newly prescribed RED drugs, ensure there is clear information as to intended mechanism for ongoing supply/ administration
  - Initiation of nutritional supplements, dressings and appliances by the provider must be included within discharge information in addition intended care plan, quantities required and at what frequencies, intended duration and review.
  - Any monitoring of medicines required including anticipated increase or decrease in dose
  - Details of medicines tried in hospital that proved unsuitable and the reason why
  - Medicines recommended for self-care or those identified as already purchasing over the counter



7.7 Patients admitted for a reason unconnected with their previous medication regimen, i.e. for surgery, the transfer information must list any drugs newly initiated and existing drugs still in use at discharge / transfer. If the remaining drugs are unchanged then the transfer notification must list **all** drugs to be continued by the patient.

7.8 Patients are given information on the prescribed medicines, how to take them and arrangements for further supply on discharge / transfer from hospital.

This will include:

- Confirmation, of which medicines have been stopped, changed and started. (i.e. a copy of the summary of transfer notification)
- Written information or information in a format they can understand, e.g. a suitable community language or audio, about obtaining further supplies of medicines including hospital only medicines.
- When necessary this may require the availability of interpreters to maximise compliance and minimise risk.

**Secondary care pharmacy professionals must ensure that:**

7.9 When a GP takes responsibility for continuing to supply drugs which are not normally available in the community, there is liaison between the transferring hospital pharmacy and the community pharmacy to ensure a continuity supply of the drug; in extreme cases, consideration may be given to wholesale procurement from the transferring hospital pharmacy whereby no other procurement methods are possible.

**Monitored dosage systems and other compliance aids**

7.10 Providers are encouraged to develop transfer planning arrangements for vulnerable patients. Where these include supply of monitored dosage or other similar systems there should be a policy in place for their use including making appropriate arrangements for continuity after transfer. Refer to section 7.2 for supply quantities.

**Secondary care pharmacy professionals must ensure that:**

7.11 Where a monitored dosage or other similar system has been deemed appropriate upon discharge/ transfer, that the prescriber and community pharmacy responsible for ongoing prescribing and supply are contacted both verbally and via email, on the day of discharge with details of the supply made including quantity and ongoing supply requirements.

**Dispensing for transfer (One Stop Dispensing)**

7.12 Providers are encouraged to employ a dispensing for transfer scheme in line with the Audit Commission report 'A Spoonful of Sugar'.

## **8. Out-patients and day cases (Planned episodes of care)**

**Primary care prescribers must ensure that:**

8.1 Patients are advised to take a list of all current medicines they are taking to all outpatient consultations to allow a comprehensive assessment by the hospital specialists.

**Secondary care prescribers must ensure that:**

8.2 Medication will be provided for outpatients in line with local and national policy as detailed below. For an outpatient prescribing referral for initiation to primary care, the request must satisfy the following criteria:

8.3 When supplying medication to patients or recommending medications for primary care to supply, providers must have regard to national guidance published by NHS England on [over the counter medicines](#) and [items that should not be routinely prescribed](#).

8.4 The drug requested must be on the Coastal West Sussex formulary and coded as 'green', for the APC approved indication it is being prescribed for and will not seek to avoid formulary restrictions by asking GP's to prescribe non-formulary medicines; nor use FP10 prescriptions as a route to prescribe non-formulary drugs

- Where a patient has an immediate clinical need for medication as a result of an outpatient consultation, the secondary care prescriber will make a sufficient supply (a minimum of 14 days) until the GP can accept responsibility for subsequent prescribing. When there is not an immediate clinical need and a prescription is not required by the patient for 14 days from the date of the outpatient appointment. The patient will be informed that the treatment is not urgent and that a prescription will not be available to collect from the general practice surgery for a minimum of 14 days from the date of the outpatient appointment.
- The indication for the medicine being requested, the key significant side-effects, the duration of treatment, follow-up and any monitoring requirements are discussed with the patient (and/or family member/carer where appropriate), and contraindications or interactions with current medication checked before discharge / transfer in addition to the provision of written supporting patient information (e.g. DOAC prescribing) should be provided if indicated.
- Written communication of the request is sent to the registered patient's general practice surgery within 7 days. The written communication to the GP should specify the indication for prescribing, name of the drug, dose, duration of treatment, any monitoring or follow-up required and who is responsible for this and any medication stopped, along with an explanation why, in addition to advice provided to the patient.

8.5 Prescribing is undertaken by the secondary care prescriber for the following:

- Medicines required for immediate treatment (i.e. initiation required within 14 days)
- Drugs agreed by the APC as hospital only (Red drugs)
- Drugs requiring hospital initiation, continued monitoring or where an agreement for shared care is pending (Blue and Amber drugs) – initial supply and for duration of stabilisation
- Hospital based clinical trials – throughout trial

- 8.6 Where a prescription is issued, a maximum of 28 days is prescribed (or original pack if 30 day pack) in line with local policy (exceptions can be found in section 7.2). Patient packs should normally be dispensed unless the full course of treatment is shorter.
- 8.7 GPs are not asked to prescribe medicines and dressings that are intended to be used in the community or administered in hospital as part of a planned procedure / episode of care, for example sedation for diagnostics or antiemetic's pre-chemotherapy. The hospital will provide medicines for immediate post-operative care, for example a short course of antibiotics or pain relief as well as medication post-radiotherapy or post-chemotherapy. This should not be confused with the use of patients own drugs (PODs) upon admission which is widely accepted practice.
- 8.8 Patients are copied into correspondence with their GP wherever possible. Secondary care clinicians should follow best practice national guidelines regarding copying of correspondence to patients (and/or their parents/carers where appropriate).

## **9. Homecare**

### **Providers (organisational) must ensure that:**

- 9.1 Providers that provide medicines through the homecare route should adhere to all national policy or guidance as a result of the Hackett Report "Homecare medicine – towards a vision for the future" including the Royal Pharmaceutical Society's Professional Standards for Homecare Services
- 9.2 Providers should have a strategy for homecare medicines developed with the local Medicines Optimisation Committee or equivalent and an annual homecare plan which the Chief Pharmacist needs to deliver in line with 9.1
- 9.3 Suitable arrangements for setting up homecare services, including the responsibilities of Providers and the CCG and funding arrangements should be clearly identified and agreed prior to setting up the service.

## **10. Dressings, appliances and enteral feeds**

### **Providers (organisational) must ensure that:**

- 10.1 Suitable local arrangements are in place for the supply of dressings, appliances and enteral feeds.

### **Secondary care prescribers must ensure that:**

- 10.2 A minimum of 7 days are provided. Sufficient information about the patient's dressings/ appliance/ enteral feed treatment must be provided as part of the transfer summary to ensure continuity of care in the community.
- 10.3 Enteral feeds must only be supplied on discharge/ transfer if accompanied with a nutritional management plan including MUST score and must be within the CWS local health economy formulary. They do not request GP's to prescribe dressings, appliances and enteral feeds outside of the CWS local health economy formulary unless there is explicit agreement between both parties. No arrangements are made by the provider

with appliance contractors for on-going supplies of dressings or appliances in the community without involving patients in the decision about where and how their further supplies are obtained. This excludes arrangements for home oxygen.

## **11. Patients attending Accident and Emergency/ Urgent Care settings**

**Secondary care prescribers must ensure that:**

- 11.1 If a medicine is necessary, a minimum of 7 days should be supplied or prescribed, unless the full course of treatment is shorter.
- 11.2 Information should reach the GP within 24 hours and should include a minimum data set for medicines reconciliation as specified in 7.5.

## **12. Unlicensed medicines used outside of their licensed indication**

- 12.1 The General Medical Council has issued this [guidance](#) for the prescribing of unlicensed and off-label medicines which is applicable to all prescribers.
- 12.2 Unlicensed medicines or medicines outside of their licence can be prescribed, when deciding to do so a prescriber must:
  - Be satisfied that an alternative, licensed medicine would not meet the patient's needs, or in the case of off-label use, be satisfied that off-label use would serve the patient's need better than a licensed alternative
  - Be satisfied that there is a sufficient evidence base and/or experience of using the medicine to demonstrate its safety and efficacy
  - Take responsibility for prescribing the unlicensed medicine and for overseeing the patient's care, including monitoring and any follow up treatment, or arrange for another doctor to do so
- 12.3 Record the medicine prescribed and, where you are not following common practice, the reasons for choosing this medicine in the patient's notes, this is applicable to all medicines prescribed for the patient, regardless of the care setting responsible for prescribing. All records must contain a complete history of all medication prescribed.
- 12.4 The patient (and/or parent/carer, where appropriate) must be given sufficient information by the initiating prescriber to allow for an informed decision/ consent to receiving an unlicensed/ off label treatment
- 12.5 The legal responsibility for prescribing rests with the healthcare professional who signs the prescription and they are professionally accountable for making this judgement and may be called to justify such actions; this is applicable, even in the case of shared care or where originally initiated by a specialist or other healthcare professional. Further guidance can be found [here](#)

**Secondary care prescribers must ensure that:**

- 12.6 When recommending the use of an unlicensed medicine or 'off-label' therapy they are responsible for ensuring that the primary care prescriber is provided with all the information needed to ensure a safe and consistent supply of product for the patient, before transferring responsibility for the prescribing of the unlicensed medicine. The roles of the GP and secondary care clinician should be clearly defined and agreed using the principles of effective shared care where deemed appropriate. This especially applies to prescribing in the Level 2 (see appendix 1) category. GPs should not be expected to take over prescribing that falls in the Level 3 (see appendix 1) category.
- 12.7 GPs should not be expected to initiate an unlicensed medicine or level 2 'off-label' therapy, and transfer of prescribing responsibility should only occur after an appropriate interval, after stabilisation has taken place (a minimum of one month's supply of medication should be provided by the initiating secondary care clinician even if prescribing responsibility is transferred earlier than this). If a GP feels unable to accept prescribing responsibility then the clinical responsibility for prescribing of that drug should remain with the secondary care clinician.

### **13. When responsibility for prescribing remains with secondary care prescribers**

Classified as **RED** in [Coastal West Sussex Local Health Economy Formulary](#)

- 13.1 The secondary care clinician is expected to retain prescribing responsibility for medicines where:
- A medicine has been commenced by the secondary care clinician and needs specialist on-going intervention and monitoring.
  - The patient receives the majority of on-going care, including monitoring, from the provider and the only benefit of transferring care would be to provider costs
  - There is no substantial body of clinically related evidence, e.g. BNF, NICE, Maudsley Guidelines to support the use of an unlicensed medicine or medicine outside of its license.
  - Drugs are subject to High-tec Hospital at Home guidance (EL(95)5).
  - Medicines are only available through the Provider trust i.e. are not available on FP10, including any 'borderline' products when used outside approved indications.
  - Medicines initiated as part of a provider initiated clinical trial or the continuance of a hospital initiated trial or compassionate use, where no arrangement has been made in advance with the purchaser to meet the extra cost of treatment.
  - The GP does not feel confident in taking on clinical responsibility for the prescribing of a drug even if a shared care prescribing agreement exists
- 13.2 If there is a disagreement about where prescribing of an individual patient's treatment should best take place the case should be referred to the CCG, via the Head of Medicines Management who will seek resolution between 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 should

be taken 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 cases.

- 13.3 Repeat prescriptions for hospital only drugs should not incur an attendance Tariff charge unless the patient receives a clinical review by a nurse or clinical specialist. The secondary care clinician should make arrangements for issuing medication in between clinical reviews as appropriate; e.g. by extending the length of prescriptions to last until the next clinical review ensuring appropriate time scales for safe and cost effective prescribing, use of FP10HP prescriptions which can be posted to the patient, arrange for the patient to collect repeat medication from the provider's pharmacy department at agreed intervals.
- 13.4 GPs should be informed of any drugs that continue to be provided by the provider. Transfer and outpatient letters should clearly state that these drugs are to be supplied by the secondary care clinician and that the GP is not expected to prescribe.

**Primary care prescribers must ensure that:**

- 13.5 A clear and comprehensive record of this information is recorded on clinical records and prescribing systems to ensure that they have a full medication history for their patients

**14. Transfer of prescribing medicines requiring specialist monitoring by GPs**

Classified as **AMBER** in Coastal West Sussex Local Health Economy Formulary

- 14.1 Increasingly, patients with continuing specialist needs can be cared for at home or in the community where the specialist considers an individual patients condition to be stable or predictable. There are medicines which a primary care prescriber may not be familiar with but could be prescribed in primary care if sufficient support, review and information is shared between the GP and secondary care clinician. All prescribers should be aware of their responsibilities to develop their own and the expertise of others in the managed introduction of new medicines.

**Secondary care prescribers must ensure that:**

- 14.2 Where a Shared Care Agreement is deemed appropriate, providers are expected to support commissioners in the development of new and update of existing agreements.
- 14.3 It is the secondary care clinician's responsibility to involve the patient and or carer in the decision to enter into shared care, explaining the principles of the agreement, in addition to exploring other options where shared care may be felt to be inappropriate by the patient and / or carer before making the shared care request, recording discussions and decisions reached.
- 14.4 It is the responsibility of the secondary care clinician to request shared care with a GP. The key principle is that the GP is provided with information and given the opportunity to decline prescribing responsibility **before** the transfer takes place.
- 14.5 It would not be expected that a GP would decline to prescribe on the basis of cost. Likewise if the patient is to receive the majority of their on-going care from the provider

then prescribing must remain with them and must not be transferred solely on the basis of cost.

- 14.6 The following conditions should be met before the shared care takes place:
- Treatment has been demonstrated to be tolerated and clinically effective.
  - Treatment is in accordance with patient-specific shared care agreement, which clearly defines the responsibilities (including specific drug details of monitoring requirements) of all parties and has been approved by the provider's Drug and Therapeutics Committee or equivalent and by the Local Health Economy's Area Prescribing Committee (with GP involvement).
  - The GP is sufficiently informed and able to monitor treatment, identify medicine interactions and adjust the dose or stop any medicines as necessary.

**Primary care prescribers must ensure that:**

- 14.7 They will inform the specialist within two weeks of receipt of the specialists's letter if unwilling to enter into shared-care arrangements. In the absence of refusal it will be assumed that prescribing responsibility will transfer and shared care arrangement is accepted

**15. Transfer of prescribing for medicines requiring initiation in secondary care**

Classified as **BLUE** in Coastal West Sussex Local Health Economy Formulary

- 15.1 these medicines are initiated by a secondary care clinician or specialist allied health professional **who holds a recognised independent prescribing qualification** and who is making recommendations within his/her area of competence. It is expected that prescribing will continue until the treatment has been demonstrated to be tolerated and clinically effective (after a minimum of 1 month unless stated otherwise within formulary); following secondary care initiation the medicine may then continue to be prescribed and monitored in any setting without a formal shared care agreement.
- 15.2 These medicines require specialist knowledge for assessment and / or equipment for patient selection but have no specialist ongoing monitoring requirements.
- 15.3 No specialist knowledge or equipment is required for ongoing prescribing or monitoring although the provision of additional information may be made where deemed necessary.
- 15.4 It may be felt to be appropriate, that a particular blue coded drug be suitable for initiation by a primary care prescriber, **upon the recommendation** of a specialist (who holds a recognised independent prescribing qualification). In this situation, an application must go to the Area Prescribing Committee for consideration. Before such recommendations can be made and initiation by the specialist must continue until the application is approved.

**Secondary care prescribers must ensure that:**

- 15.5 Although formal shared care arrangements are not required in these instances, sufficient information is provided to the primary care clinician to enable the undertaking of

prescribing in primary care confidently without compromising patient care. The provision of additional information may be made where deemed necessary.

- 15.6 Where it is felt that a particular drug may be appropriate for initiation in primary care, on the basis of a specialist's recommendation, an application should be completed (available [here](#)) with the support of respective pharmacy team and then submitted to the CWS Area Prescribing Committee for approval. This should consider the financial impact of the recoding upon the relevant care setting, the resulting effect on primary and secondary care and all related issues including delivery of care, commissioning and procurement arrangements and may require clinical experts within the field to present or provide further information to enable full consideration.

## **16. Non-Medical Prescribing**

- 16.1 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.
- 16.2 The provider must ensure that non-medical prescribers:
- are 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.
- 16.3 Specialist nurses who do not hold an independent prescribing qualification should refer to their supervising clinician if a prescription is indicated.

## **17. Tertiary care referrals**

- 17.1 It is normally 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 specifications. If NHS specialised commissioning services are providing an advisory service for the assessment and development of a treatment plan only before transferring back to the referrer, the original referrer is responsible for making prescribing decisions in relation to the referral. GPs should only be asked to prescribe drugs initiated by tertiary care referrals if this is compliant with all criteria listed above and in sections 13, 14 and 15.
- 17.2 Where it is clinically appropriate for a patient to be cared for at home, under the supervision of the tertiary centre, the centre should make appropriate arrangements for prescribing and supply of specialist medicines (e.g. High-tec home health schemes EL(95)5 or use FP10HPs).
- 17.3 In some circumstances it may be more appropriate to transfer prescribing to more local providers or more rarely a GP. In all situations there should be robust processes and agreement in place between the tertiary centre, secondary care clinician and GP's to



ensure timely and accurate transfer of a patient's medication details to appropriate professionals responsible for his/her care.

(Local providers have the right to not prescribe medicines initiated by a tertiary centre if what is recommended falls outside of local guidance, this needs to be made clear. Also patients referred to tertiary and also private specialists must be made aware by their GP before they attend that a medicine started by the private or tertiary specialist may not necessarily be prescribed locally if it does not fit in with local guidance and then either they will have to use a locally agreed NHS alternative or get their tertiary/private specialist to prescribe it).

- 17.4 GPs should be informed of any drugs that continue to be supplied by the provider. Discharge and outpatient letters should clearly state that these drugs are to be supplied by the provider and that the GP is not responsible for prescribing but should however be documented within the patients medication history within the practice patient records.

## **18. Subcontracting to a Third Party Provider**

- 18.1 Commissioners recognise that providers may wish to explore alternative methods of service delivery and medication supply e.g. outsourcing of outpatient dispensing, provision of a hospital service by an out of area provider. However for all services and medicines supply, the provider and subcontractor must ensure that they meet the medicines management standards and follow governance processes for CWS prescribers. Commissioners must be included in any such discussions and finally agree any subcontractor arrangements.

## **19. Formulary**

- 19.1 The commissioners and providers jointly support the classification of medicines and newly introduced medicines onto the market through the [Coastal West Sussex Local Health Economy Formulary](#) and expect prescribers to work in line with this classification.
- 19.2 If secondary care clinicians or GPs wish to prescribe medicines that are not currently included within the local health economy formulary or are supported by specialist prescribing from tertiary centres, they should submit a request to the Coastal West Sussex Area Prescribing Committee for evaluation and possible inclusion in the formulary or alternatively for an individual patient an Individual Funding Request (IFR) can be made as appropriate.
- 19.3 There may be patient specific occasions whereby it is deemed clinically appropriate for a primary or secondary care clinician to prescribe a non-formulary medicine, in such instances the rationale for taking this decision must be clearly documented within the patient's records. If there is any doubt as to the appropriateness of prescribing a non-formulary medicine, further advice may be sought from the hospital pharmacy team or CCG medicines management team.

## **20. Clinical trials**

- 20.1 All clinical trials must have been subject to the research ethics committee approval, when the arrangements for consulting and informing should be considered. Trials should also

have been through the local or regional NHS Research Governance process. This should take account of whether or not the trial is in line with strategic objectives of the organisation (for research and clinical care) and any continued supply of medicines at the end of the trial if required.

- 20.2 In order to respond appropriately to any suspected adverse events that occur outside the hospital setting, the GP should be adequately informed if a patient is participating in a clinical trial following patient consent.
- 20.3 Prescribing and supply of clinical trial medicine is the responsibility of the Provider. 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 normally include the cost of the trial medicines either during or after the trial unless specifically agreed with the commissioner. Any excess treatment costs will also need to be agreed with the commissioner.
- 20.4 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 should continue, post-trial costs will only be funded where prior agreement has been reached with the commissioner(s).

## ***Categorisation of unlicensed medicines***

<b>Category</b>	<b>Prescribing status</b>
<b>Level 1. Lower Risk Preparations</b>	<p><b><i>Unrestricted General Use</i></b></p> <p>A Level 1 risk preparation must be either purchased from a manufacturer with a MHRA manufacturer's (specials) licence (who has a licence to produce this type of product), or has a licence in a country in the EEA, USA or country with a mutual recognition agreement <sup>1</sup>, and is one of the following:</p> <ul style="list-style-type: none"> <li>• A preparation produced under a 'specials' license where the licensed formulation is unsuitable for a particular patient e.g. liquid preparation for administration via a PEG tube. Otherwise the product is used within the terms of the MA.</li> <li>• A preparation listed in the BNF or Children's BNF, or any other approved national recommendations.</li> <li>• A preparation obtained as an alternative to near patient aseptic manipulation e.g. pre-made chemotherapy IV products.</li> <li>• Any other preparation assessed to be low risk e.g. most unlicensed topical preparations and preservative-free preparations of preserved licensed ophthalmic preparations.</li> </ul> <p>Off-label use of a medicine where that use is acknowledged as usual practice by reference in either the BNF, Children's BNF or any other relevant and credible national source or guideline.</p>
<b>Level 2. Intermediate Risk Preparations</b>	<p><b><i>General use with restrictions</i></b></p> <p>An unlicensed medicine not in the Level 1 or Level 3 category which is either:</p> <ul style="list-style-type: none"> <li>• A preparation licensed in the EEA, USA or country with a mutual recognition agreement, or</li> <li>• A preparation purchased from a manufacturer with a manufacturer's (specials) licence, where there is good evidence to support its use and no serious safety concerns</li> </ul> <p>Moderate risk 'off-label' use relates to where there is some evidence to support its use and there are no significant concerns relating to its safety.</p>
<b>Level 3. Higher Risk Preparations</b>	<p><b><i>Specialist use only</i></b></p> <p>For unlicensed preparations:</p> <ul style="list-style-type: none"> <li>• Any preparation manufactured outside of the EEA, USA or a country with a mutual recognition agreement.</li> <li>• Any preparation that is manufactured in the EEA, USA or country with a mutual recognition agreement, but is not licensed in that country.</li> <li>• Any other preparation where there are serious concerns over safety, but the benefits are still judged to outweigh the risks.</li> </ul> <p>Higher risk 'off-label' use is when there are concerns relating to safety, but it is agreed that the benefits of treatment this way outweigh the risks.</p>

<sup>1</sup> Australia, Austria, Belgium, Bulgaria, Canada, Cyprus, Czech Republic, Denmark, Estonia, Finland, France, Germany, Greece, Hungary, Iceland, Ireland, Italy, Japan, Latvia, Liechtenstein, Lithuania, Luxembourg, Malta, Netherlands, New Zealand, Norway, Poland, Portugal, Romania, Slovakia, Slovenia, Spain, Sweden, Switzerland, USA.