Community Dispensing Enzaltumide

Service Level Agreement

1. INTRODUCTION

1.1

This framework provides an umbrella Service Level Agreement (SLA) and acts as a contract between NHS Fife and the pharmacy contractor and commits the contractor to provide the services as defined by, and using documents provided in, the individual service pack for each medicine which must be read in conjunction with this Service Level Agreement. Services will be provided within the legal and ethical framework of pharmacy as a whole.

1.2

The introduction of tiered service specifications for medicines prescribed by secondary care will provide a contractual and governance framework for NHS Fife and their community pharmacy partners to supply medicines traditionally supplied via the hospital dispensary or homecare with enhanced pharmaceutical care provision where needed.

1.3

The national approach to designing these services is new and will need Boards and contractors and their representatives to work collaboratively in order to deliver high quality pharmaceutical care to the patients of Scotland. As with all new things there is a need for all stakeholders to work flexibly and recognise the needs of all parties in the delivery of improved patientcare. In designing services Boards will be mindful of any impacts on contractors not related to the delivery of pharmaceutical care and seek to mitigate, minimise or resolve such burdens where possible. As such this umbrella agreement and the individual service packs that sit underneath it will be reviewed regularly and feedback and the use of improvement approaches will be welcomed.

1.4

The details of how care is delivered, responsibilities are defined,care provided, delivery monitored and contracts paid will form part of the individual service pack for eachmedicine. These will form part of the framework as medicines are approved for addition to the framework.

2. BACKGROUND TO SERVICE

2.1

The investment made by the NHS in medicines is for the explicit purpose of delivering health gain to the population. For this investment to bring the best possible outcomes for the people who are prescribed these medicines, pharmaceutical care of the correct quality has to be delivered reliably, safely, effectively and efficiently. The 2011 regulations to the National Health Service (Pharmaceutical Services) (Scotland) Act, places a duty on Boards to secure adequate pharmaceutical care services for the patients within their boundaries. Where medicines are prescribed by secondary care services to outpatients, it may be appropriate for the specified pharmaceutical care to be provided by community pharmacy or homecare. The placement of community pharmacies and their integration within the local healthcare system may mean that they are the preferred route of service provision.

2.2

Pharmaceutical Care Services, provided by community pharmacy, for patients receiving medicines supervised by secondary care has a number of advantages over traditional homecare services:

- Service provision is more likely to be fully integrated with other local services delivered within the local healthcare system.
- Access by vulnerable populations is facilitated, including those with less stable lifestyles and the homeless.
- Effective communication is promoted betweencommunity pharmacy, general practice and the secondary care service.
- Such provision supportsand accelerates familiarity with use of these newer medicines within the community setting.
- Ensuring that patients' medicines are provided within the context of other medicines prescribed in primary care and the pharmaceutical care needs of the patient.
- Supports the validityand reliability of the communitypharmacy held pharmaceutical care record.
- Enables assessment of patients' needs for compliance support and delivery of enhanced support where required as part of the patient's clinical management plan.

2.3

The national arrangements to provide pharmaceutical services, that all local NHS pharmacy contractors are obliged to provide, includes provision for the supply of medicines in response to a prescription from secondary care. However, these arrangements allow a pharmacy contractor to source medicines to fulfil a prescription from wherever they see fit, subject to the requirements to deliver a product of suitable quality. For almost all of the medicines to be delivered under this agreement there is a primary care rebate scheme in place. These commercially confidential schemes ensure that the net prices paid by a Health Board for a medicine traditionally supplied by secondary care is the same if it is moved to primary care. In order to access these rebate schemes and for rebates to be paid the medicine supplied must be purchased through distribution arrangements put in place by the manufacturer that has been contracted to supply the product to the NHS, sometimes from a specific wholesaler. NHS Boards will reconcile manufacturers supply data with the reimbursement information from PSD to ensure adherence to these distribution arrangements. Clearly NHS Boards cannot allow the price to be paid for the medicine to exceed that which we would incur in secondary care so this agreement makes a specific requirement on contractors to supply products under this agreement that are sourced as described in each service pack.

2.4

For many outpatient medicines the national arrangements for the provision of pharmaceutical care will be appropriate. However, in supplying a small proportion of these medicines there may be a range of governance related issues that should be considered and addressed to support both the smooth supply of medicines and to facilitate local pharmacists discharging their clinical and professional responsibilities.

2.5

It is useful to ensure that all stakeholders are clear about their responsibilities to one another in pursuit of the provision of medicine supply and pharmaceutical care relating to medicines prescribed by the hospitalservice to outpatients. It is for this reason that these arrangements are included in this specification.

2.6

This umbrella framework specification outlines the generic elements common to each tier of the service and the requirements that should be met within local agreements.

3. SERVICE AIMS

3.1

The central aim of the service to provide patients with access to medicines prescribed from the hospital service along with any associated pharmaceutical care support deemed appropriate by the NHS Board from a local community pharmacy contracted to provide NHS services on behalf of the NHS Board.

3.2

The supplementary aims include:

- Ensuring that suitable education materials are provided or signposted. Providing community pharmacists with links to appropriate supportwithin the hospital service to access advice or resolve care issues.
- Ensuring that any supplies can be reliablyaccessed by community pharmacy contractors
- Ensuring that medicines supplied in this way are sourced and supplied effectively and efficiently for the NHS i.e. to protect any primary care rebate that is in place

4. SERVICE OUTLINE AND STANDARD

4.1 Tier 1

4.1.1

Where a medicine supply and any associated pharmaceutical care requirement falls wholly within the scope of the national pharmacy arrangements but the Health Board wishes to direct where the medicine should be sourced through distribution arrangements put in place by the manufacturer that has been contracted to supply the product to the NHS these supplies will attract a Tier 1 engagement fee.

4.2 Tier 2

4.2.1

Tier 2 is designed for those medicines and patients that require enhanced pharmaceutical care over and above that contracted for within the national arrangements. Currently this enhancement tends to focus on compliance support with examples including compliance monitoring and reporting or arrangements for patient consumption to be observed on the contractor's premises. However, this tier will also cover areas where specific secondary-care-led patient assessments are required, where pharmacy staff may administer or supervise administration of a medicine and where additional measures are required to support effective medicines adherence.

4.2.2

Current models underdevelopment in pharmaceutical care include drug and disease monitoring including the taking of bloods and interpretation and care planning resulting from laboratory results. It could also include undertaking disease measurement to monitor disease control that is usually measured within an outpatient clinic setting.

4.2.3

This specification sets out the framework for these enhancedarrangements within Tier 2. The individual service pack for each medicine will define any pharmaceutical care bundle and explicitly describe the roles and responsibilities of the pharmacist / pharmacy team over and above the scope of the national Pharmaceutical Care Service arrangements.

4.2.4

An example of a Tier 2 service already provided within NHS Boards is the agreement to supply medicines for the treatment of patients with Hepatitis C. These arrangements include a pharmaceutical care fee reflecting the additional compliance support and compliance monitoring and reporting that helps support patients to achieve improved treatment outcomes or to support an assessment for treatment model of care. Tier 2 services will attract a Tier 1 engagement fee plus an additional pharmaceutical care fee.

4.3 Tier 3

4.3.1

Tier 3 describes those services that currently are provided for via homecare or might form part of a hospital at home solution where such services are being devised. Medicines and regimens in this tier would be those that require a significant level of pharmaceutical care beyond that traditionally provided by community pharmacy teams. This tier would provide an alternative to traditional homecare routes of supply for medicines that require, for example, direct cold chain supply to patients supplemented by administration of injectable medicines and follow up monitoring in the patient's home or training the patient to self administer. Often medicines in this tier will require the input of non pharmacy staff or very specialist pharmacy input and requires multiagency cooperation and coordination. It is anticipated that tier 3 would need to be resourced for those elements of service over and above the national arrangements.

5. ROLES AND RESPONSIBILITIES

5.1

For all medicines provided under these arrangements it is important that the roles and responsibilities of the secondary care services and community pharmacy are explicitly clear. These roles and responsibilities will be defined within the individual service pack for each medicine.

5.2

Where a medicine is classified as a systemic anti-cancer treatment (SACT) additional care is needed to ensure that local arrangements explicitly define the responsibilities of the community pharmacist and specialist pharmacy team based in the hospital service. In particular Service Level Agreements for SACT will define responsibilities as described in the British Oncology Pharmacists Association (BOPA) publication 'Standards for Pharmacy Verification of Prescriptions for Cancer Medicines' (2013), Scottish Government Health Department CEL 30 (2023) and the NHS Safety Alert (NPSA 2008).

6. USE OF PHARMACEUTICAL CARE BUNDLES

6.1

Evidence-based care bundles provide a structured way of improving the processes of care and being explicit about patient outcome delivery. Care bundles are a small, straightforward set of evidence-based practices, generally three to five, which, when performed collectively and reliably, can improve patient outcomes.

6.2

Care bundles are best developed using consensus methodologies with input and guidance from a range of stakeholders.

6.3

Care bundles can be used to set out the roles and responsibility that each healthcare professional/setting has in the delivery of care for the patient. Such explicit definition of roles and responsibilities can allow complex or specialist care to be delivered across providers in a seamless way. Design of care bundles should normally be under the leadership of the relevant Specialist Interest Group or through NHS board-wide cooperation.

7. TRAINING REQUIREMENT

7.1

Tier 1: It is anticipated that other than in exceptional circumstances specific training for the supply and pharmaceutical care relating to Tier 1 medicines should not be required. It is recognised that a number of these medicines will not be historically routinely dispensed by community pharmacists and each medicine will be supported by an individual service pack. However, as with other new medicines dispensed in primary care, community pharmacists should make themselves aware of the available information on these medicines.

7.2

Tier 2 & 3: Training will be dependent upon the standard of pharmaceutical care defined by the Board and the pharmaceutical care bundle being contracted along with the competence and confidence of local contractors to deliver the bundle. Where training is a prerequisite of service delivery this will normally be reflected in any service fee agreed upon for Tiers 2 and 3.

8. MONITORING AND EVALUATION

8.1

Tier 1 will be monitored through submission of claims forms. Under the agreement pharmacy contractors will be required to confirm that they have complied with any requirements concerning the sourcing of medicines supplied. Payment verification will be used to validate claims for individual contractors. Contractors will be required to maintain procurement records for supplies made under this agreement for 2 years following supply for the purposes of payment verification.

8.2

Tiers 2 and 3 will require bespoke monitoring and audit with appropriate KPIs reflecting the care bundles contracted for in addition to the requirements relating to Tier 1.

8.3

Where a pharmacy has supplied a medicine from a source not specified or approved in the individual service pack for each medicine the Health Board retains the right to reclaim the appropriate service fee and make a claim against the contractor for the loss of primary care rebate.

9. CLAIMS AND PAYMENT

9.1

The process of claiming service remuneration should be as simple as possible and electronic where practicable.

9.1.1

Local arrangements will specify dates for submission of claims, procedures for dealing with late claims, payment verification processes, details of any appeal procedures and identification of key contacts for financial issues to be raised with. Claims should be sent by the 5th of each month to fife.fifepharmacycommpharm@nhs.scot.

9.2 Service remuneration

The engagement fee for Tier 1 will be £75 per patient, per year / course of treatment if less than a year. NHS Fife, in agreement with Community Pharmacy Fife will pay an additional £45 per patient per year in recognition of the uplift in community pharmacy costs since the original framework was agreed.

Service management Boards should recognise the administrative burden that they may place on contractors relating to service provision and should seek to minimise this burden where possible. Where such administration relates to the delivery of pharmaceutical care, measurement of care bundles or is required as part of payment processes or NHS payment verification requirements these should be within the pharmaceutical care service fee.

In general prescriptions should reflect standard quantities supplied in primary care e.g., 28 / 56 days.

Arrangements should be mindful of particularly expensive treatments where monthly prescriptions may be required to mitigate contractor cash flow issues.

9.3 Reimbursement

Reimbursement of medicine acquisition costs will be through standard methods, including arrangements for advanced payments that are in place nationally. All medicines that are supplied under the service level agreement regardless of Tier should:

- Be accessible to purchase by all contractors on the Pharmaceutical List .
- Have the reimbursement cost of the medicine clarified; in particular any zero discount status should be made clear before any arrangements are in place.

For most prescriptions this will be the standard national script submission and reimbursement processes. For high cost medicines, those where the item cost is over £1000,the standard advance payment system provides a mechanism for contractors to receive early payment.

In exceptional circumstances service arrangements may include provision for advance of the entire treatment course where this has an exceptionally high acquisition cost. The only example to date where this is required is for the provision of treatment of patients with hepatitis C where acquisition costs for the course of treatment may reach almost £40,000.

9.4 General business costs

General business costs such as insurance, servicing finance, banking charges, business administration, payment tracking, etc are reflected in national arrangements for community pharmaceutical services and as such do not form part of local arrangements / service level agreements.

It is anticipated that many of the medicines prescribed by secondary care and supplied via community pharmacy under this framework will be available from major wholesalers / through existing account arrangements and will require no, or minimal additional workload, around account set up, payment tracking, administration etc. However, where such non-pharmaceutical care related impacts are significant and are envisaged, or occurring, local discussions on such impacts may need to take place.

10. RISK

10.1

Many of the treatments that Boards may wish to see dispensed in community pharmacy rather than in the hospital will be of greater cost than the average prescription item dispensed by the contractor. Service level agreements should explicitly describe those scenarios out with the control of the contractor for which the Board / prescriber will take financial responsibility for e.g. patients not completing their course of treatment, patients losing their medication.

10.2

Contractors should always remain accountable for delivery of their professional responsibilities and standards e.g. incorrect ordering of a medicine would fall beneath the threshold at which a Board / prescriber would be expected to take financial responsibility, although Boards should where possible attempt to utilise such medication for alternative patients

APPENDIX

GENERAL INFORMATION

Approved Name	Enzalutamide
Brand Name	Xtandi
Manufacturer Name	Astellas Pharma Ltd

Indication this proposal relates to	For treatment of adult men with metastatic hormone-sensitive prostate cancer (mHSPC) For the treatment of adult men with high-risk non-metastatic castration-resistant prostate cancer (nmCRPC). Treatment of adult men with metastatic castration-resistant prostate cancer (mCRPC)
Costs of Treatment	£2,734.64 for 112 x 40mg (1 month treatment)
Acquisition Parity	Astellas will supply to community pharmacy. Enzalutamide held on PSD database. Enzalutamide flagged as zero discount on dm&d to ensure correct payment.
Barriers to community acquisition	Astellas use Alliance as their sole provider for procurement for enzalutamide. Terms will be as for any other drug procured through this route. Pharmacies must register with Astellas via telephone initially but then can order directly through Alliance.
Medicines formulation and route of administration	Oral soft capsule
Dosing information	The recommended dose is 160mg (4x40mg capsules) as a single daily dose. Capsules should be swallowed whole with water and can be taken with or without food. Treatment is continued until progression or unacceptable toxicity.
Storage Requirements	No specific storage requirements
SMC status	SMC2400 - For treatment of adult men with metastatic hormone-sensitive prostate cancer (mHSPC) in combination with androgen deprivation therapy. SMC2195 - For the treatment of adult men with high-risk non-metastatic castration-resistant prostate cancer (nmCRPC). High-risk is defined as prostate specific antigen (PSA) doubling time (PSADT) ≤10 months and PSA ≥2 ng/mL.
Expected patent expiry	2028
Patient Access Scheme status	A PAS in place. Rebates are done retrospectively based on usage. NHS Boards have their own mechanisms in place.

Prescribing arrangements	Prescribing will take place in secondary care at the patient's oncology clinic. Prescriptions may be written by a consultant oncologist, a medical registrar or staff grade or a non-medical prescribing nurse or pharmacist. Patients will nominate a single community pharmacy at which they will receive their enzalutamide. This community pharmacy will be the only supplier of enzalutamide for this patient. Full details of each patient's nominated community pharmacy will be kept on a database held by the Secondary Care Team The nominated community pharmacy will be contacted by the prescribing team with information about the patient and their current medication. They will also be provided with details on how to order and enzalutamide. Prescriptions will be written on an HBP and given to the patient to deliver to the community pharmacy. Patients will be seen at clinic at 2, 4, 8 or 12 week intervals and be given prescriptions at these appointments. Each prescription will be for 4 weeks supply. If patients are seen at 8 or 12 week intervals, they will receive two or three separate prescriptions for 4 weeks supply respectively. Patients will only collect 4 weeks supply at a time. Prescriptions will be forward dated to prevent the supply of more than 4 weeks at a time. The first supply of enzalutamide will be from the hospital pharmacy and will be for 5 weeks supply. This builds in an extra week's supply to allow the community pharmacy time to order enzalutamide upon receipt of the HPB without disrupting supply to the patient. Treatment will continue until disease progression or unacceptable toxicity. Decision to stop treatment will be made at the oncology clinic and the community pharmacy involved will informed by the secondary care team.
Scope of service	This service would be offered to all patients receiving enzalutamide in NHS Fife. There may be individual patients who due to personal circumstances it will not be possible to proceed with community dispensing of enzalutamide. This will be reviewed on an individual patient basis.
Anticipated number of patients using the service	NHS Fife currently processes approximately 65 prescriptions per month for enzalutamide
Proposed tier of service to be provided	Tier 1 – No additional Pharmaceutical Care required out with the normal dispensing and supply of a new drug to the patient.
Outline of any pharmaceutical care bundle to be delivered	It is expected that community pharmacists will: Provide pharmaceutical care including support with adherence. Under MCR, create a PCR for each patient if they do not have one already, and document relevant issues as they arise. Liaise with GP/secondary care team if any new acute/routine medicines are prescribed that may significantly interact with enzalutamide. Notify the secondary care team of any concerns regarding the patient or any adverse events relating to enzalutamide. Advise the patient to contact their GP/triage/ Cancer Treatment Helpline if signs of infection/felling unwell. Notify the secondary care team if the patient does not collect their enzalutamide when expected.
Outline of training requirements to be made as part of an SLA	Each pharmacy will designate a named pharmacist to be responsible for the on-going delivery of the scheme. The named pharmacist providing the service should read the service protocol and accompanying information and operate within the service specifications. Other staff should have general awareness that the service is in place to ensure continuity of service where possible. Pharmacy contractors are free to develop their own standard operating procedures to deliver the scheme in their own pharmacy.

Requirement for a clinical information sheet	Community pharmacies will receive an information sheet which will include information on the need for the service. It will also include contact details, specific dispensing and labelling requirements and information on when to contact the secondary care team. Community pharmacists are expected to consult the SPC for information specific to enzalutamide.
Responsibilities of initiating consultant	Patients will be reviewed and consented for treatment by an oncologist responsible for their care. The first supply of enzalutamide will be from the hospital pharmacy and the patient will receive the appropriate education and counselling, with a baseline assessment of drug interactions with current medication. Patients will be reviewed regularly at the oncology clinic, every 2, 4 or 8 weeks depending on clinical status. Patients will have the opportunity to return to clinic earlier than planned at the discretion of the secondary care team. Patients will receive regular scans, which will be used in conjunction with patient review to determine the appropriateness of continuing treatment. It is not anticipated that there will be a requirement for regular communication with the community pharmacy, however the community pharmacy details for each patient will be kept on a database held by the Oncology Pharmacy Secondary Care Team.
Responsibilities of community pharmacist	Ensure that the supply of the drug to the patient is made in a timely manner using the correct route of supply from the identified supplier. Respond accordingly to the instruction and direction of the prescriber.
Disposal of waste	Enzalutamide is hormonal treatment. It is not cytotoxic and therefore disposal arrangements are the same as for any other medicine.
Responsibilities of the patient	Whilst there are no specific storage requirements for enzalutamide, it should be kept in a safe place, out of the reach of children and where it cannot be confused with other medication. Report any adverse drug reactions at clinic visits or, if urgent contact the triage line/Cancer Treatment Helpline as appropriate. Keep clinic appointments for monitoring and follow up. Check any new OTC medicines are safe to take, with the community pharmacist. Agree to take enzalutamide as prescribed and collect supplies as arranged. Notify the team of any missed doses.
Patient education and communication	Patients will receive counselling on how to take the medication and potential side effects by the secondary care team. Patients will sign consent prior to commencing treatment. Patients will receive contact details and information on what to do in the event of emergency/ side effects.
Clinical governance	Any incidents or dispensing errors should be recorded as per standard procedures in the community pharmacy. Details of incidents or dispensing errors must be communicated with the secondary care team as soon as is possible. Where appropriate the patient must also be contacted as soon as possible. In the event of any ADRs the secondary care team must be notified and if appropriate the patient's GP. If a patient is unwell they must be advised to seek help immediately by contacting their GP, triage, cancer treatment helpline or the emergency services as appropriate.
Performance measurement	Patient and staff satisfaction survey following service implementation.

Contingency Arrangements	In the event that a particular community pharmacy can no longer provide the service, the secondary care team must be contacted and will arrange either for a supply from the hospital pharmacy or a transfer of care to another community pharmacy that is convenient for the patient.
Specialist service resources required to support the service	Completion of initiation and change in treatment forms. Completion of HBP prescriptions. Liaison with community pharmacies.
Community pharmacy service resources required to support the service	Dispensing and ordering of medication. Liaison with secondary care.
Funding	All prescribing will take place via HBP. As enzalutamide is over £1000 it can be subject to an advanced payment via PSD using the recognized method through the Primary Care Pharmacy Team.
Payment	Annual payment will be arranged between secondary care team and community pharmacy once patient agreed to change in supply provider and registered with named community pharmacy. Secondary care team will monitor patient cohort noting when patient(s) receives cycles 11 and/or 12 triggering next annual payment.