Service Specification No.	11X-49
Service	The Supply of Inhaler Spacer Devices
Commissioner Lead	Somerset Clinical Commissioning Group
Provider Lead	Avon Healthcare Services Ltd
Period	1 April 2021-31 March 2024
Date of Review	August 2021

1. Population Needs

National/local context and evidence base

- 1.1 The key objective of this specification is to ensure that when community pharmacists review a patient's inhaler technique, they give advice on the most suitable type of inhaler. If the preferred device forms part of the pMDI (pressurised metered dose inhaler) pathway, the Minor Ailment Scheme will allow supply of a spacer device if deemed beneficial to the patient.
- 1.2 Spacers minimise the need for perfect co-ordination when inhaling and are particularly recommended where high doses of inhaled steroids are used.

2. Outcomes

2.1 NHS Outcomes Framework Domains & Indicators

Domain 1	Preventing people from dying prematurely	
Domain 2	Enhancing quality of life for people with long-term	
	conditions	
Domain 3	Helping people to recover from episodes of ill-health or	✓
	following injury	
Domain 4	Ensuring people have a positive experience of care	✓
Domain 5	Treating and caring for people in safe environment and	✓
	protecting them from avoidable harm	

2.2 Local defined outcomes

Not Applicable

3. Scope

Aims and objectives of service

- 3.1 This specification covers all patients (children and adults) who:
 - are deemed to be appropriate for an pMDI pathway for their condition
 - are using a bronchodilator or inhaled corticosteroid or combination of both
 - are giving consent to GP being informed a spacer has been supplied
 - are registered with a Somerset GP
 - Patient has agreed to an inhaler technique review by the community pharmacist
 - Following that inhaler technique review the community pharmacist and patient agree that a spacer would aid better technique and outcomes from their pMDI inhaler.

- 3.2 Patients taking a mix of pMDI and dry powder inhalers (DPI) should be recommended for review in GP practice to synchronise to one type or another before a spacer is supplied.
- 3.3 Spacers should not be supplied to patients under this Specification using both a DPI and pMDI.

Benefits of the Scheme

- 3.4 The service will aim to provide the following benefits:
 - Reduced referrals to GP practice for spacer
 - Improved inhaler technique
 - Improved patient outcomes
 - Reduction in waste.
- 3.5 This service is intended to support patients to gain maximal benefit from their prescribed medicines, and is not designed to be a replacement for the annual asthma or COPD review in the GP practice.
- 3.6 In children, a pMDI and spacer are the preferred method of delivery of β2 agonists and inhaled corticosteroids. A face mask is required until the child can breathe reproducibly using the spacer mouthpiece.

Spacers to be Supplied

3.7 These are spacer devices in the Somerset formulary, namely Easychamber®: with or without mask (175ml capacity), Aerochamber Plus®: Standard device with or without mask (149ml capacity), Aerochamber Plus Flow-Vu Antistatic, with or without mask or Volumatic® Spacer (750ml capacity). This is reimbursed at the September 2021 BNF cost (see below) for the spacer.

Item	Price
Easychamber adult with mouthpiece	£3.98
Easychamber with adult mask	£6.59
Easychamber with infant mask	£6.53
Easychamber with child mask	£6.55
Aerochamber Plus	£5.06
Aerochamber Plus with adult, child or infant face	£8.44
mask	
AeroChamber Plus Flow-Vu Anti-Static	£5.22
AeroChamber Plus Flow-Vu Anti-Static with	£8.72
adult small mask	
AeroChamber Plus Flow-Vu Anti-Static with	£8.72
adult large mask	
Volumatic	£3.88

Use and Care of Spacers

- 3.8 The spacer should be compatible with the pMDI being used. A change in spacer may alter effective dose delivered.
- 3.9 Spacers should be cleaned monthly or performance is adversely affected. They should be washed in detergent and allowed to dry in air. The mouthpiece should be wiped clean of detergent before use.

3.10 Plastic spacers should be replaced at least every 12 months but some may need changing at six months.

Action Once Spacer is Supplied

- 3.11 It is a requirement to keep auditable records of administration and supply of medication and devices via this Specification.
- 3.12 Information entered into a patient clinical record should include:
 - Patient's name, address and date of birth
 - Consent given
 - Indication
 - Name of device supplied
 - Date supplied
 - Information and advice given to the patient on use and maintenance of device
 - Signature/name and GPhC number of pharmacist who supplied the medication, and name and address of pharmacy
 - Record that medicine supplied via Specification
 - A computer or manual record of all individuals receiving treatment under this Specification should also be kept for audit purposes within each practice. Check with employer which method of recording is to be used.
 - The GP practice should be informed of the consultation and supply of medication.
 - Data must be stored in accordance with Caldicott guidance, GDPR and the Data Protection Act.

Characteristics of Staff / Quality Assurance

- 3.13 Pharmacist must be registered with the General Pharmaceutical Council (GPhC) and competent to work with this Specification.
- 3.14 Must have completed initial training and/or be familiar with the current service level agreement for Somerset Minor Ailments Service.
- 3.15 Must be able to themselves demonstrate good inhaler technique with a pMDI with and without a spacer.
- 3.16 Must only use this specification in conjunction with the Somerset Minor Ailments Service.
- 3.17 Must have access to a current copy of the BNF (British National Formulary).
- 3.18 Consultation room available for discussion.
- 3.19 The individual pharmacist's competence with respect to their practice under this Specification will be assessed by their mentor/manager on a regular basis.
- 3.20 It is the responsibility of the pharmacist to keep up-to-date with their continued professional development, in line with GPhC requirements.

3.21 The pharmacist must be alert to changes in Summaries of Product Characteristics, and Drug Safety Updates from MHRA.

Further Guidance

- 3.22 Patients taking high dose ICS should be advised to carry a steroid warning card.
- 3.23 Advice on mouth hygiene should be offered to avoid side effects.
- 3.24 Asthmatic patients to be reminded that step-down considerations are part of the asthma pathway and that doses should be just enough to control symptoms.
- 3.25 Asthma UK guide to spacers including videos (https://www.asthma.org.uk/advice/inhalers-medicines-treatments/inhalers-and-spacers/spacers/)

Infection control

- 3.26 Providers must have infection control policies that are compliant with national guidelines and current handling protocols, including but not limited to The Health and Social Care Act 2008 Hygiene Code (refer to 4.1) and which takes into account:
 - disposal of clinical waste,
 - needle stick incidents,
 - environmental cleanliness, and
 - standard precautions, including hand washing.

Audit and Reporting

Significant/adverse events

- 3.27 The Department of Health emphasises the importance of collected incidents nationally to ensure that lessons are learned across the NHS. A proactive approach to the prevention of recurrence is fundamental to making improvements in patient safety.
- 3.28 The Provider should be aware of (and use as appropriate) the various reporting systems such as:
 - the NHS England National Reporting and Learning System. Reports to NRLS can be submitted via the Somerset CCG medication incident reporting system, or the national GP e-form. If using the GP e-form please check the box to share your report with Somerset CCG. For details of the Somerset CCG Medication Incident reporting form see paragraph 3.25,
 - the Medicines and Healthcare products Regulatory Agency reporting systems for adverse reactions to medication (yellow card system), and accidents involving medical devices; and
 - the legal obligation to report certain incidents to the Health and Safety Executive under the Reporting of Injuries, Diseases and Dangerous Occurrences Regulations (RIDDOR)
- 3.29 In addition to their statutory obligations, the Provider will notify the Commissioner within 72 hours of being aware of the hospital admission or death of a patient being treated by the Provider under this enhanced service.
- 3.30 In addition to any regulatory requirements the CCG wishes the Provider to use a Significant Event Audit system (agreed with the Clinical Commissioning Group) to facilitate the dissemination of learning, minimising risk and improving patient care and safety. Providers shall:

- Report all significant events to the CCG, within 2 working days of being brought to the attention of the Provider,
- Undertake a significant event audit (SEA) incorporating root cause analysis using a tool approved by the CCG and forward the completed SEA report to the CCG within one month of the event.

Reporting

- 3.31 The Provider will ensure appropriate systems are in place to measure the quality and performance of the service on a continuous basis.
- 3.32 Information will be provided in the quarterly and annual report submitted for the Minor Ailment Scheme, which summarises the activity of the service. This will include, but is not limited to:
 - The number of patients managed within the service,
 - Age, registered GP practice, and spacer supplied for each patient.

Service user and public involvement

- 3.33 Service users should be involved in the decisions about their care and given high-quality information to enable them to make fully informed decisions regarding their ongoing care.
- 3.34 The Provider should encourage, consider and report any service user feedback (positive and negative) on the service that they provide and use it to improve the care provided to patients, particularly if there are plans to alter the way a service is delivered or accessed.

Pricing

- 3.35 Patients will receive the spacer free of charge.
- 3.36 Payment to the pharmacy will be £10 for completing the review where a spacer device is prescribed, plus the cost of the spacer as above.
- 3.37 Only 1 spacer will be allowed per patients via this specification

Any acceptance and exclusion criteria and thresholds

3.38 N/A

Interdependence with other services/providers

- 3.39 Local General Practice
- 3.40 Secondary Care
- 3.41 Public Health
- 3.42 Community Pharmacy

4. Applicable Service Standards

4.1 Applicable national standards (e.g. NICE)

The Health and Social care Act 2008: Code of practice on the prevention and control of infection and related guidance.

4.2 Applicable standards set out in Guidance and/or issued by a competent body (eg Royal Colleges)

Current edition of British National Formulary (BNF);

Current edition of the BNF for children;

General Pharmaceutical Council. Standards of conduct, ethics and performance (Current version available at www.pharmacyregulation.org/);

General Pharmaceutical Council. Standards for continuing professional development (Current version available at www.pharmacyregulation.org/);

General Pharmaceutical Council. Guidance: Consent (Current version. Available at www.pharmacyregulation.org/);

General Pharmaceutical Council. Guidance: Patient Confidentiality (Current version. Available at www.pharmacyregulation.org/);

General Pharmaceutical Council. Guidance: Raising concerns (Current version. Available at www.pharmacyregulation.org/);

General Pharmaceutical Council. Guidance: Responding to complaints and concerns (Current version. Available at www.pharmacyregulation.org/);

Medicines Act 1968 (as amended)

NHS Executive (2000) Patient Group Directions [England only]. Health Service Circular HSC 2000/026. (Available at www.dh.gov.uk);

Royal Pharmaceutical Society of Great Britain (2005) The Safe & Secure Handling of Medicines: A Team Approach. London, RPSGB. (A revision of the Duthie Report 1988) (Available at www.rpharms.com);

Summaries of Product Characteristics (SPCs) (Available at www.medicines.org.uk);

4.3 Applicable local standards

Not applicable

5. Applicable quality requirements and CQUIN goals

N/A

Location of Provider Premises

5.1 The Provider's Premises are located at:

As per the Particulars of the NHS Standard Contract