

Specials Prescribing Optimisation Tool List (SPOT-List)

The Specials Prescribing Optimisation Tool (SPOT) is based on the national specials prescribing data. This list includes:

- Specials that appear regularly in the top fifteen most prescribed.
- Specials where there has been a significant growth in prescribing.
- Specials that may not appear very often but when they do pose significant cost pressure due to their expense.

This bulletin aims to provide information on how to optimise prescribing either by offering alternatives, or by suggesting how to contain prescribing of the particular special. Further supporting resources and bulletins are available to support implementation of the recommendations within this bulletin at <https://www.prescqipp.info/headline-areas/specials>. However, as with all prescribing, these bulletins are general recommendations and any decisions on what to prescribe should be tailored to the individual patient. The prescriber is directly responsible for the prescribing of these unlicensed products and will be liable for adverse effects or harm resulting from the use of that product.¹

Background

A special is an unlicensed medicine that does not have either a centrally authorised Marketing Authorisation in the European Union, or a UK Marketing Authorisation. It is manufactured, imported or supplied to meet the special clinical needs of an individual patient.²

A special may only be supplied when there is no available licensed medicine which fully meets the patient's clinical needs. They can be prescribed when it is judged by the prescriber and agreed with the patient or carer that, on the basis of available information, a special is the most appropriate option for the patient.² The Medicines Act allows appropriate prescribers to prescribe medicines without a licence providing they are happy to assume full liability for the prescription.¹

There are certain clinical situations where a special may be judged to be the most appropriate or only available option, for example:

- For children, e.g. they are routinely prescribed to achieve the lower doses required.²
- In dermatology, e.g. unlicensed creams and ointments containing tars, dithranol, salicylic acid, steroids and other active constituents in a range of concentrations and bases for psoriasis, eczema and a small number of miscellaneous conditions.³
- In ophthalmology, e.g. preservative-free eye drops.²
- For patients intolerant or allergic to a particular ingredient.⁴
- For patients who require alternatives to solid dosage forms that are not available as a licensed oral liquid.²

Issues associated with specials

There are several issues associated with specials, which affect both prescribers and pharmacists.

Licensing

The Human Medicines Regulations 2012 requires a medicine placed on the market in the UK to hold a Marketing Authorisation (MA). Medicines with an MA have been approved by the European Commission or Medicines and Healthcare products Regulatory Authority (MHRA). Appropriate standards of quality, safety and efficacy are met, provided the medicine is used in accordance with the terms of its MA.² For the medicine to obtain an MA the pharmaceutical companies have to provide evidence of the effectiveness; expected side effects; stability; any interactions; bioavailability; acceptability and safety of the formulation.¹ The evidence is obtained from human trials and by demonstrating that the procurement, manufacturing and storage conditions within the manufacturing and distribution elements of the production process are appropriate and safe.¹ The MA, previously known as a Product Licence must be displayed on the pack and provides a guarantee of quality.¹ Specials are unlicensed medicines, and so will not have been assessed by the licensing authority for safety, quality and efficacy. Usually they are specially prepared to meet a prescription ordered for individual patients, without the need for the manufacturer to hold an MA for the medicinal product concerned.

Legal

If a prescriber uses a medicine within the terms of the licence, as specified in the Summary of Product Characteristics (SPC) any untoward effects are the legal responsibility of the manufacturer. If a patient experiences a side effect (including those not specified in the SPC) then the patient would have grounds to prosecute the manufacturer. This is not the case for a pharmaceutical special. As there is no SPC the prescriber takes full responsibility in law for any adverse effect caused by the medicine, unless it can be demonstrated that the medicine was faulty. Given the uncertainties explained above this should not be underestimated. The prescriber should be able to justify and feel competent in using such medicines.¹ The prescriber is responsible because the medicine is unlicensed and has been made to their specifications.

Professional responsibility and accountability

The primary professional responsibility of a prescriber and pharmacist is to ensure the safety of the patient.¹ The General Medical Council (GMC) has guidance for prescribers relating to unlicensed medicines. When prescribing an unlicensed medicine you must:

- Be satisfied that there is sufficient evidence or experience of using the medicine to demonstrate its safety and efficacy.
- Take responsibility for prescribing the medicine and for overseeing the patient's care, monitoring, and any follow up treatment, or ensure that arrangements are made for another suitable doctor to do so.
- Make a clear, accurate and legible record of all medicines prescribed and, where you are not following common practice, your reasons for prescribing an unlicensed medicine.⁵

The Royal Pharmaceutical Society (RPS) has published a professional guidance, available here: www.rpharms.com/support-pdfs/rps---specials-professional-guidance.pdf for the procurement and supply of pharmaceutical specials. The guidance consists of five principles and supports pharmacists and their teams to work with prescribers, patients and carers to ensure the safe and appropriate procurement and supply of specials.²

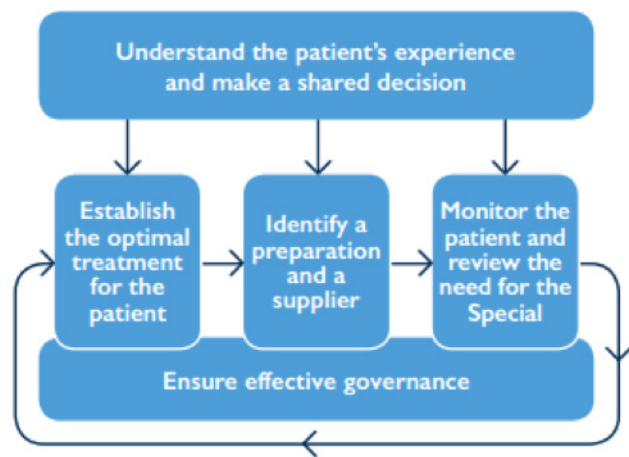


Figure 1. Five principles for the procurement and supply of specials

1. Establish the optimal treatment for the patient

All treatment options are evaluated. Prescribers and pharmacists work together to ensure that specials are only supplied when the patient has a special clinical need that cannot be met by an available licensed medicine (this special clinical need does not include reasons of cost, convenience or operational need).

2. Understand the patient's experience and make a shared decision

The patient's needs, values and preferences are discussed to ensure that the implications and practicalities of supplying and using specials are understood, and that patients (or carers) are supported to adhere to their medicines.

3. Identify a preparation and a supplier

When procuring and supplying a special, pharmacists ensure that patients receive medicine that is of appropriate quality, is appropriate for the patient's condition and personal circumstances, with minimal clinical risk.

4. Monitor the patient and review the need for a special

The appropriateness of continued prescribing of a special is reviewed to ensure that it remains the best option and ongoing supply is justified by the patient's continued special clinical need.

5. Ensure effective governance is in place

Governance arrangements are in place to support the safe and effective procurement and supply of specials in order to provide consistently safe and effective specials to treat patients.

The guidance contains a series of statements and case studies that describe examples of good practice that support the application of these principles in practice.²

Quality and efficacy

Specials can be sourced from a variety of suppliers or manufacturers. Consequently the quality and consistency of the product can vary considerably. This can lead to potential differences in pharmacokinetics and clinical responses, which may have a negative impact on patient safety. This is particularly important for drugs with narrow therapeutic windows.

Cost

There is no set pricing for pharmaceutical specials, and there is no national pricing structure governing these products or local regulation of the cost of products to the NHS. As use of specials increases, there is a growing financial burden on the NHS. However in Part VIII B of the Drug Tariff (Arrangements for payment for specials and Imported Unlicensed Medicines) there is a tariff of high volume and high cost unlicensed specials and imports. This includes set reimbursement prices on a selection of specials. The prices are set by analysis of a selection of unlicensed specials manufacturer's prices, with a margin included for pharmacy purchase profit.⁶ When an unlicensed special or an imported medicine which is listed in Part VIII B is prescribed, the pharmacy contractor will be reimbursed the set Drug Tariff price for dispensing the product, no matter how the product is sourced.⁶ Specials listed in Part VIII B of the Drug Tariff have a minimum quantity, a price for that quantity and a price per subsequent 1ml or 1g (unless

in a special container).⁷ Currently the Drug Tariff states that acetazolamide 250mg/5ml oral suspension costs £144.60 for 100ml (minimum quantity) and every 1ml extra will cost 4p.⁷ So using acetazolamide 250mg/5ml oral suspension as an example:

- If the quantity is below the Part VIII B listed minimum volume, reimbursement will be the price for the minimum volume. For example if 50mls of acetazolamide 250mg/5ml oral suspension is ordered on prescription, the pharmacy will be paid £144.60.
- If the quantity is equal to the minimum volume, reimbursement will be the price for the minimum volume, e.g. if 100mls is ordered on prescription the pharmacy will be paid £144.60.
- If the quantity prescribed is more than this minimum volume, reimbursement will be paid on that price plus the 1ml (or 1g) list price for the additional amount prescribed. E.g. if 200mls of acetazolamide 250mg/5ml oral suspension was ordered on prescription the pharmacy will be paid £144.60 for £100ml and every 1ml extra will cost 4p, therefore the total cost for 200mls would be £148.60.^{6,7}

Please note there is currently no Part VIII B to the Drug Tariff in Northern Ireland. Therefore there are no set reimbursement prices for any specials.

An additional fee of £20.00 is paid to the pharmacy for dispensing unlicensed medicines including:

- Preparations manufactured under an MHRA specials licence or sourced under an MHRA importers licence.
- Preparations prepared under the Section 10 exemption from the Medicines Act 1968.⁷

Considerations for the prescribing, procurement and supply of specials

When choosing suitable preparations for a patient the prescriber must consider:

- Clinical appropriateness for the patient
- Product quality and licensed status
- Cost.

When deciding whether to prescribe an unlicensed product, the first consideration should be to determine if a medicine is needed at all. Any unnecessary medicines should be stopped. If a liquid formulation of a medication is required, consider agents with a prolonged therapeutic effect (but not modified or slow-release preparations) to reduce the frequency of dose administration.⁸ As a pharmacist shares with the prescriber accountability for supplying a special to a patient they have a professional responsibility to liaise with the prescriber and the patient or carer, to ensure that a special is (and remains) the most appropriate choice. For example, would a different licensed medicine in the same class or a different class of medicine be suitable for the patient? A newly licensed medicine may have become available, or the patient's condition may have changed.²

The ideal situation is to prescribe an appropriate UK licensed medication. If a licensed product is not suitable; consider off-label use of a UK licensed medication. This could be off-label as it is outside of the licensed indications or because the tablet has been crushed and dispersed or the capsule has been opened. Consult product literature to see if this is a licensed option. This may not be a suitable option for all patients; consideration should be given to whether the patient or carer is able to administer medication in this manner and the dose required as drawing off aliquots from a dispersed product is not ideal but may sometimes be necessary.

Where healthcare staff are administering these medicines, consideration should be given to providing written information or a protocol for the administration of medicines by unlicensed methods of administration. Individuals may require training and may need advice on health and safety issues particularly if medication is to be crushed or capsules opened. It is important that the prescriber writes brief instructions for administration on the prescription, e.g. "via PEG".

Useful resources to identify the ability of crushing, dispersing tablets/ capsules for nasogastric (NG) feeding are:

- Handbook of Drug Administration via Enteral Feeding Tubes
- The NEWT Guidelines

The MHRA published guidance in May 2014 on the supply of unlicensed medicinal products (“specials”) which can be found at: www.gov.uk/government/publications/supply-unlicensed-medicinal-products-specials. This document contains guidance on the hierarchy for the use of unlicensed medicines, however each patient should be considered on their individual needs.

Table 1- Hierarchy of risk based on product origin⁴

Risk	
1	An unlicensed product should not be used if a UK licensed medicine is available which meets the patient’s special need.
2	An “off label” (outside of the licensed indications) use of a UK licensed product, if this can meet the clinical need, should be used instead of an unlicensed product.*
3	If a UK product cannot meet the special need, then an imported medicinal product should be considered, which is licensed in the country of origin.
4	If none of the above options will suffice, then a completely unlicensed product may have to be used, for example, UK manufactured “specials”, which are made in GMP inspected facilities, but which are otherwise un-assessed (GMP inspection of “specials” manufacturers is not product specific). There may also be other products available which are unlicensed in the country of origin.
5	Products that are unlicensed in the country of origin, and which are not classed as medicines in the country of origin. For example, the use of products from countries where they are classed as supplements, not pharmaceuticals, and may not be made to expected standards of pharmaceutical GMP. These should be avoided whenever possible.

* Licensed products available in the UK have been assessed for quality safety and efficacy. If used “off-label” some of this assessment may not apply, but much will still be valid. This is better than the use of an un-assessed, unlicensed product. The fact that the intended use is outside of the licensed indications is therefore not a reason to use an unlicensed product. It should be understood that the prescriber’s responsibility and potential liability are increased when prescribing off-label.

The RPS guidance has a checklist (appendix 3) for dispensing specials based on the five guiding principles that support the procurement and supply of specials. The checklist can be used as a starting point for pharmacists and their teams to develop their own local checklists.

What is the patient’s special clinical need?

1. Why is the patient being prescribed a special?
2. Is there a need to make contact with the prescriber to discuss:
 - » If the prescriber is aware that the prescription is for a special?
 - » Alternatives to the special?
 - » The formulation of the product?

Understand the patient’s experience.

3. If the patient has not had the special before are there any specific patient requirements (e.g. special containers, measuring devices)?

4. Is there a need to discuss with the patient:
 - » Likely timescales for the supply and the need to request a repeat prescription in good time?
 - » How and when to order repeat prescriptions from their GP?
 - » The shelf life/in-use shelf life of the special? Is this on the label?
 - » Quantities they need to order?
 - » Why specials are different to licensed products?
 - » Changes to the supplier or formulation that may alter the way the special is taken or used (e.g. a change in concentration)?

Identify a preparation and supplier.

5. Does the pharmacy previously supplying the special need to be contacted to confirm the formulation (e.g. hospital, different community pharmacy)?
6. If the patient has had the special before can the same supplier be used to ensure consistency?
7. Has the formulation been fully agreed with the supplier? Including any particular requirements (e.g. sugar free, alcohol free, flavourings?). Should this be confirmed with the supplier in writing?
8. Has information to support the quality of the special been obtained? E.g. Certificate of Analysis or Conformity?
9. Have the supplier's details been entered into the patient's record?

Ensure effective governance.

10. Has national and/or local guidance been followed?
11. Have all records been completed in line with MHRA and organisational requirements?
12. Have the organisation's relevant Standard Operating Procedures (SOPs) been followed?

Monitor and review.

13. What are the arrangements for reviewing the patient's prescription?
14. Does the patient's condition or the special mean that they require closer monitoring?
15. Is there any cause for concern about the patient's treatment?
 - » Any adverse events?
 - » Any indication of treatment failure?

SPOT-List

The SPOT-List contains the top fifteen medicines (all formulations and strengths) supplied as specials ranked by total spend nationally. The total spend on specials is approximately £22.3 million (based on ePACT data for total prescribing in England Oct-Dec15 and Wales Apr-Jun16). The top fifteen specials represent approximately £12.8 million of this total spent. For some of the items listed in the top 15, there are several formulations and strengths within the indicator.

Table 2 - The 15 chemical substances covered in the SPOT-List

Melatonin	Other Individually Form Bought In Preps (see "unspecified drug codes" below for more information)	Omeprazole	Magnesium Glycerophosphate	Midazolam Maleate
Glycopyrronium Bromide	Liothyronine Sodium	Trientine Dihydrochloride	Diltiazem Hydrochloride	Acetylcysteine
Phenobarbital	Sodium Chloride (including eye preparations)	Colecalciferol	Levomepromazine Maleate	Levothyroxine Sodium

SPOT-List supporting information

The supporting information provided in the tables on the following pages is intended as a guide for healthcare professionals reviewing prescribing of specials.

Please note this is not an exhaustive list of products available.

Prices of medicines may vary depending on handling fees and changes in Drug Tariff price. Please note where a Drug Tariff price is referred to this applies to England and Wales only as currently there is no Part VIII B to the Drug Tariff in Northern Ireland. The use of a licensed alternative product may be outside of its licence, so off-label, but a preferred option based on the MHRA's hierarchy for the use of unlicensed medicines. Please refer to the SPC or manufacturer for licensing information.

For all the specials listed, the continued need for the special should be the first consideration when reviewing treatment. See PrescQIPP's Polypharmacy and Deprescribing webkit and Improving Medicines and Polypharmacy Appropriateness Clinical Tool (IMPACT) for further guidance: www.prescqipp.info/

Drug	Potential alternative (licensed, off-label or unlicensed)	Information for oral use (For enteral feeding please consult The Handbook of Drug Administration via Enteral Feeding Tubes)	Hierarchy of risk based on product origin	Average cost per item (ePACT Apr - Jun 2016)	Total spend on specials (ePACT Apr - Jun 2016)
Other individually form bought in preps*		These are products with unspecified drug codes. See below for more details.		£61	£3,470,015
Melatonin Melatonin (SPOT-List) bulletin is available here: www.prescqipp.info	Circadin® 2mg MR tablets	Where prolonged-release melatonin is indicated and the patient can swallow capsules, consider off-label use of Circadin®. Licensed as monotherapy for the short-term treatment of primary insomnia characterised by poor quality of sleep in patients who are aged 55 or over. If used in children it would be unlicensed use. No high-quality studies were identified that provided evidence for the efficacy of prolonged-release melatonin tablets (licensed in the UK) used off-label in children with sleep disorders and attention deficit hyperactivity disorder (ADHD). ⁹ Consider discussion with secondary care specialist, consider shared care.	2	£81	£3,107,997

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<p>Omeprazole</p> <p>Omeprazole (SPOT-List) bulletin is available here: www.prescqipp.info</p>	Losec® MUPS®	<p>Are licensed and can be dispersed it in a spoonful of non-carbonated water, mixed with some fruit juices or apple sauce.¹⁰</p> <p>Patients should be advised that the tablets should not be dispersed in milk or carbonated water. ¹⁰</p> <p>The enteric-coated pellets must not be chewed. ¹⁰</p> <p>Price in Drug Tariff is available for unlicensed oral solution.</p>	1	£86	£961,102

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Midazolam maleate	Buccolam Oromucosal solution	<p>Buccolam (midazolam, as hydrochloride) is licensed for the treatment of prolonged, acute, convulsive seizures in infants, toddlers, children and adolescents (from 3 months to <18 years).¹¹ Buccolam must only be used by parents/carers where the patient has been diagnosed to have epilepsy.¹¹</p> <p>Doses available as 2.5mg, 5mg, 7.5mg & 10mg pre-filled syringes.¹²</p> <p>For infants between 3-6 months of age, treatment should be in a hospital setting where monitoring is possible and resuscitation equipment is available.¹¹</p> <p>Buccal midazolam may be considered as an alternative to rectal diazepam for the treatment of prolonged seizures. Various buccal midazolam preparations have been used in children as unlicensed medicines, including Buccolam prior to receiving market authorisation.¹³</p> <p>Buccolam is half the strength of some other unlicensed preparations. It contains the hydrochloride salt; some other preparations contain the maleate salt. Although there is some suggestion that the maleate salt may be better absorbed in the buccal cavity, there are adequate studies with midazolam hydrochloride to support the dosing schedule authorised for Buccolam.¹³</p> <p>A hospital paediatric unit has recently published its experience of transferring patients to licensed Buccolam. One of the key points raised was the requirement to have only one product (specifically only one strength) of product available for use.¹⁴ This would be to ensure no confusion during dosing, and should be considered prior to switching patients to licensed product.</p>	1	£188	£899,229

Drug	Potential alternative (licensed, off-label or unlicensed)	Information for oral use (For enteral feeding please consult The Handbook of Drug Administration via Enteral Feeding Tubes)	Hierarchy of risk based on product origin	Average cost per item (ePACT Apr - Jun 2016)	Total spend on specials (ePACT Apr - Jun 2016)
Magnesium glycerophosphate	Magnaspartate® oral powder sachets	<p>Magnesium-L-aspartate (Magnaspartate®) is the preferred choice for the treatment and prevention of magnesium deficiency when clinically appropriate as it is the only UK licensed oral magnesium preparation for these indications.¹⁵</p> <p>One 6.5g Magnaspartate® sachet contains magnesium aspartate dihydrate equivalent to 243mg (10 mmol) of magnesium and is indicated in adults, children and adolescents aged from 2 years.¹⁶</p> <p>If Magnaspartate® is not effective in raising magnesium levels or if it is poorly tolerated it is reasonable to try an alternative oral magnesium preparation.¹⁵</p> <p>However caution is required when switching between magnesium preparations, swapping on a mmol for mmol basis may not result in an equivalent therapeutic effect as magnesium preparations have differing bioavailability.¹⁵</p> <p>Robust evidence of the superiority of one oral magnesium preparation over another does not exist; therefore it is not possible to recommend one particular preparation over another on the basis of efficacy and safety. Large scale clinical outcome studies are needed.¹⁵</p> <p>Price in Drug Tariff is available for unlicensed oral solution.</p>	1	£138	£852,392
	YourMAG	<p>Magnesium Glycerophosphate 97.2mg (4mmol) chewable caplets maybe an alternative for existing patients that can't be switched to magnesium aspartate.</p> <p>It is a registered food supplement.</p> <p>It is manufactured to GMP standards and made following the european pharmacopoeia monograph for chewable magnesium glycerophosphate yourproducts.co.uk/products.html</p>	5		

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Colecalciferol	Desunin tablets/ Fultium-D3 and Plenachol capsules/ InVita, Thorens and (Thame Laboratories Ltd) oral solution.	For treatment of vitamin D deficiency recommended dose is 800 units (iu) daily, although higher doses may be necessary for severe deficiency. ¹² There are several preparations available reimbursement is based on the following brands in the Drug Tariff: Desunin 800iu tablets. Fultium-D3 800iu, 3,200iu and 20,000iu capsules/Plenachol 40,000iu capsules. InVita D3 25,000iu and 50,000iu/Thorens 10,000iu/ml sugar free oral solution/colecalciferol 15,000iu/5ml oral solution (Thame Laboratories Ltd). Licensed oral drops: Thorens 10,000iu/ml sugar free oral drops. ⁷ Prices in Drug Tariff for unlicensed variations. ⁷	1	£20	£563,946
Glycopyrronium bromide	1mg and 2mg tablets.	Licensed for use in adults as add-on therapy in the treatment of peptic ulcer. ¹⁷	2	£115	£532,875
	200 micrograms/ml injection	The BNF for Children states for administration by mouth, injection solution may be given or crushed tablets suspended in water. ¹⁸ This is outside the licensed indication, so would be considered off-label use.	2		
	Cuvposa® 1mg/5ml oral solution	Licensed in the US to treat chronic severe drooling in children and young people aged 3–16 years with a neurological condition. ¹⁹ Costs will vary as the product is imported. Price in Drug Tariff is available for unlicensed oral solution.	3		

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Liothyronine sodium	20 micrograms tablets	Used for the treatment of myxoedema coma, the management of severe chronic thyroid deficiency and hypothyroid states occurring in the treatment of thyrotoxicosis. ²⁰ Levothyroxine sodium (thyroxine sodium) is the treatment of choice for maintenance therapy. ¹² 20microgram tablets are scored. ¹²	1	£60	£482,510
	20 micrograms powder for solution for injection	The dose for elderly patients and children is 5micrograms daily. The tablets can be crushed and triturated with lactose for administration as a powder. ²⁰	2		
		Injection is indicated for the treatment of myxoedema coma. ²¹	1		

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Diltiazem hydrochloride Topical diltiazem (SPOT-List) bulletin is available here: www.prescipp.info/ (log in required)	Rectogesic® glyceryl trinitrate 0.4% rectal ointment	<p>Majority of the spend on diltiazem is for topical preparations, so the recommendations are for topical products only.</p> <p>Currently, 0.4% glyceryl trinitrate rectal ointment (Rectogesic®) is the only licensed treatment in the UK. It is indicated for the relief of pain associated with chronic anal fissure in adults, but is not licensed for children or young people under 18 years.²²</p> <p>Rectogesic® ointment can be used as a licensed alternative, a finger covering should be used when applying.²³</p> <p>Topical 0.2% glyceryl trinitrate ointment does not currently have a UK licence for treating chronic anal fissures, or for any other indication. Therefore, its use is unlicensed.²²</p>	1 - for pain relief 2 - for treatment of chronic fissures	£345	£360,579
	Anoheal® diltiazem 2% cream	<p>SLA Pharma Ltd (UK) makes this unlicensed special, and it can be ordered directly from the manufacturer at a cost of £42 per 30g tube with £5 delivery cost.²⁴</p> <p>However, even if prescribed as Anoheal® and endorsed as Anoheal® the prescription will still be reimbursed at the price in the Drug Tariff, i.e. £68.93 for 30g.^{7,25}</p> <p>Anoheal® is in the DM+D (dictionary of medicines and devices) as an invalid listing.²⁶</p> <p>Price in Drug Tariff is available for unlicensed 2% ointment and cream.</p>	4		
Phenobarbital	15mg/5ml elixir.	<p>This formulation is licensed, but contains 38% alcohol.²⁷</p> <p>MHRA/CHM Advice – For Category 1 drugs, doctors are advised to ensure that their patient is maintained on a specific manufacturer’s product.²⁸</p>	1	£311	£341,828

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Acetylcysteine	N-Acetyl Cysteine NAC, Solgar N-Acetyl Cysteine or YourNAC 600mg capsules YourNAC 600mg tablets	Majority of the spend is for oral formulations, so the recommendations for oral products only. 600mg capsules can be purchased from some health food shops. This is a food supplement, and has not undergone a quality assurance assessment as licensed medicines do.	5	£100	£289,401
	Various	IDIS are able to order as a special if prescribed. ²⁹	5		
Trientine dihydrochloride	300 mg capsules	Licensed in UK for treatment of Wilson's disease in patients intolerant of penicillamine. ¹²	1	£5,277	£269,510
Sodium chloride	Oral preparations	Licensed tablets available as Slow Sodium 600mg (approx. 10 mmol each of Na ⁺ and Cl ⁻). ¹²	1	£79	£229,944
		Licensed sodium chloride oral solution 292.5mg/5ml (1mmol/ml) is listed in the Drug Tariff in Northern Ireland. ³⁰	3		
		Price in Drug Tariff is available for unlicensed oral solution.	4		
	Eye preparations	Sodium chloride special order eye drops – no longer classified as an unlicensed medicine as there are several prescribable medical devices available. ³¹ Licensed 0.9% single use (preservative-free) eye drops are available. ⁷ 5% eye drops and 5% preservative-free eye drops now available as registered medical devices. ⁷ Sodium chloride 5%w/w eye ointment available medical devices. ³¹ Prescriptions need to be endorsed with one of the products listed in Part IXA. ³²	1		

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Levothyroxine sodium	100micrograms/5ml oral solution, 25, 50 and 100 microgram tablets	Majority of the spend is for capsules and liquid specials. Levothyroxine sodium is available as 100 micrograms/5ml sugar free oral solution, 25, 50 and 100 microgram tablets. ⁷	1	£259	£ 204,912
Levomepromazine maleate	Nozinan® 25mg tablets	Licensed tablets are scored. Macmillan Cancer Support advise that the 25mg tablets can be quartered for a starting dose of 6.25mg. ^{33,34}	1	£208	£202,168

* See unspecified drug codes below

Unspecified drug codes

Unspecified drug codes refers to products that have been prescribed, but have not yet been added or cannot be added to the internal NHS Business Service Authority drug database and is therefore captured as unspecified.³⁵ There should be a significant decline in the number of items shown as Unspecified Drug Code, as the majority of unlicensed products will be captured using the appropriate record on the NHS database.³⁶ The NHSBSA can provide details of unspecified items with a net ingredient cost (NIC) of £60 or over to named contacts in the Clinical Commissioning Group.³⁵

References

1. PrescQIPP NHS programme and the NHS East of England Collaborative Procurement Hub. Information and Guidance on the Prescribing and Use of Unlicensed Specials v3.1. March 2013. Accessed 18/03/2016 Available online at: www.prescqipp.info/headline-areas/specials
2. Royal Pharmaceutical Society of Great Britain. Professional Guidance for the Procurement and Supply of Specials. December 2015. Accessed 18/03/2016 Available online at: www.rpharms.com/support-pdfs/rps---specials-professional-guidance.pdf
3. The British Association of Dermatologists. Specials Recommended by the British Association of Dermatologists for Skin Disease. 2014. Accessed 21/03/2016 Available online at: www.bad.org.uk/healthcare-professionals/clinical-standards/specials
4. Medicines and Healthcare products Regulatory Authority. The supply of unlicensed medicinal products ("specials"), MHRA Guidance Note 14. 2014. Accessed 22/03/2016 Available online at: www.gov.uk/government/uploads/system/uploads/attachment_data/file/373505/The_supply_of_unlicensed_medicinal_products__specials_.pdf
5. General Medical Council. Good Practice in Prescribing Medicines and Devices: Unlicensed Medicines. 2013, Updated April 2014. Accessed 22/03/2016 Available online at: www.gmc-uk.org/guidance/ethical_guidance/14316.asp
6. The Pharmaceutical Services Negotiating Committee. Unlicensed specials and imports. Accessed 08/04/2016. Available online at: psnc.org.uk/dispensing-supply/dispensing-a-prescription/unlicensed-specials-and-imports/
7. Drug Tariff, April 2016. Accessed 08/04/2016. Available online at: www.ppa.org.uk/ppa/edt_intro.htm
8. UKMI Q&A 294.3. What are the therapeutic options for patients unable to take solid oral dosage forms? Date prepared: July 2013. Accessed 11/04/2016. Available online through NICE Evidence Search at: www.evidence.nhs.uk
9. National Institute of Health and Care Excellence. NICE advice [ESUOM2]. Sleep disorders in children and young people with attention deficit hyperactivity disorder: melatonin. January 2013. Accessed 14/04/2016. Available online at: www.nice.org.uk/advice/esuom2/chapter/Key-points-from-the-evidence
10. Summary Product Characteristics. Losec MUPS Tablets 20mg. AstraZeneca UK Limited. Last Updated on eMC 04th January 2016. Accessed 14/04/2016. Available online at: www.medicines.org.uk/emc/medicine/7431
11. Summary Product Characteristics; Buccolam 2.5mg, 5mg, 7.5mg and 10 mg oromucosal solution. Shire Pharmaceuticals Limited. Last Updated on eMC: 10th November 2016. Accessed 14/04/2016. Available online at: www.medicines.org.uk/emc/medicine/25538
12. British National Formulary. April 2016. Accessed 14/04/2016. Available online at: www.medicinescomplete.com/mc/bnf/current/
13. Medicines and Healthcare products Regulatory Authority (MHRA). Drug Safety Update: Buccal midazolam (Buccolam▼): new authorised medicine for paediatric use. October 2011. Accessed 14/04/2016. Available online at: www.mhra.gov.uk/Safetyinformation/DrugSafetyUpdate/CON131931
14. Tomlin, S. Medicines Tailored for Children: The Introduction of Buccal Midazolam. The Pharmaceutical Journal. 4th August 2011; 287: 161. Accessed 14/04/2016. Available online at: www.pharmaceutical-journal.com/opinion/comment/medicines-tailored-for-children-the-introduction-of-buccal-midazolam/11081706.article
15. UK Medicines Information (UKMI) Q&A 111.5. What oral magnesium preparations are available in the UK and which preparation is preferred for the treatment and prevention of hypomagnesaemia? Date prepared: 8th April 2015. Accessed 14/04/2016. Available online through NICE Evidence Search at: www.evidence.nhs.uk
16. Summary Product Characteristics. Magnaspartate 243mg Powder for Oral Solution. Kora Healthcare. Last Updated on eMC 01st April 2015. Accessed 14/04/2016. Available online at: www.medicines.org.uk/emc/medicine/30238
17. Medicines and Healthcare products Regulatory Authority (MHRA). Summary Product Characteristics; Glycopyrronium Bromide 1mg Tablets. Morningside Healthcare Ltd. Date of revision of the text: 21st March 2016. Accessed 16/04/2016. Available online at: www.mhra.gov.uk/home/groups/spcpil/documents/spcpil/con1459314225341.pdf

18. British National Formulary for Children. April 2016. Accessed 16/04/2016. Available online at: www.medicinescomplete.com/mc/bnfc/2011/
19. National Institute of Health and Care Excellence. NICE advice [ESUOM15]. Hypersalivation: Oral glycopyrronium bromide. July 2013. Accessed 16/04/2016. Available online at: www.nice.org.uk/advice/esuom15
20. Summary Product Characteristics; Liothyronine Sodium BP 20micrograms Tablets. Amdipharm Mercury Company Limited. Last Updated on eMC: 04th April 2016. Accessed 16/04/2016. Available online at: www.medicines.org.uk/emc/medicine/24153
21. Summary Product Characteristics; Liothyronine Sodium BP 20micrograms Injection. Amdipharm Mercury Company Limited. Last Updated on eMC: 14th December 2015. Accessed 16/04/2016. Available online at: www.medicines.org.uk/emc/medicine/25628
22. National Institute of Health and Care Excellence. NICE advice [ESUOM7]. Chronic anal fissure: 0.2% topical glyceryl trinitrate ointment. March 2013. Accessed 17/04/2016. Available online at: www.nice.org.uk/advice/esuom7/chapter/Key-points-from-the-evidence
23. Summary Product Characteristics. Rectogesic 4 mg/g Rectal Ointment. ProStrakan. Last Updated on eMC 01st October 2015. Accessed 17/04/2016. Available online at: www.medicines.org.uk/emc/medicine/16174
24. Personal Communication via email correspondence: SLA Pharma Ltd UK- 18th April 2016.
25. PrescQIPP. Topical diltiazem (SPOT-List). Bulletin 133. April 2016. Accessed 18/04/2016 Available online at: www.prescqipp.info/news/newsfeed/bulletin-133-launched-diltiazem-2-cream-spot-list
26. NHS Business Services Authority. Dictionary of Medicines and Devices (DM+D). Accessed 18/04/2016 Available online at: apps.nhsbsa.nhs.uk/DMDBrowser/DMDBrowser.do
27. Summary Product Characteristics. Phenobarbital 15mg/5ml Elixir. Thornton & Ross Ltd. Last Updated on eMC 01st February 2016. Accessed 18/04/2016. Available online at: www.medicines.org.uk/emc/medicine/25384
28. Drug Safety Update Medicines and Healthcare products Regulatory Authority (MHRA). Drug Safety Update. Antiepileptic drugs: new advice on switching between different manufacturers' products for a particular drug. 14th November 2013. Accessed 18/04/2016. Available online at: www.gov.uk/drug-safety-update/antiepileptic-drugs-new-advice-on-switching-between-different-manufacturers-products-for-a-particular-drug
29. Doncaster and Bassetlaw Hospitals. N-Acetylcysteine. July 2010. Accessed 18/04/2016 Available online at: www.dbh.nhs.uk/Library/Patient_Information_Leaflets/WPR32830%20Acetycysteine.pdf
30. Business Service Organisation. Drug Tariff Northern Ireland, May 2016. Accessed 19/05/2016. Available online at: www.hscbusiness.hscni.net/services/2034.htm
31. The Royal College of Ophthalmologists and the UK Ophthalmic Pharmacy Group. Ophthalmic Special Order Products, General Principles. November 2015. Accessed 18/04/2016. Available online at: www.rcophth.ac.uk/2015/11/ophthalmic-special-order-pharmacy-products-guidance-updated/
32. Coastal West Sussex Clinical Commissioning Group. Alternatives to prescribing unlicensed pharmaceutical special-order products ('specials') for adults. Version 24. July 2015. Accessed 18/04/2016. Available online at: www.coastalwestsussexformulary.nhs.uk/
33. Summary Product Characteristics. Nozinan tablets. Sanofi. Last Updated on eMC 02nd March 2015. Accessed 18/04/2016. Available online at: www.medicines.org.uk/emc/medicine/6603
34. Macmillan Cancer Support. Primary Care 10 Top Tips - Vomiting in cancer. Accessed 18/04/2016. Available online at: www.macmillan.org.uk/documents/aboutus/health_professionals/primarycare/10toptips/10toptipsvomiting.pdf
35. NHS Business Service Authority. Hints and tips information services. Issue 16. Accessed 22/04/2016. Available online at: [www.nhsbsa.nhs.uk/Documents/PrescriptionServices/Information_Services_-_Issue_16_\(Final\)_2_07_2014.pdf](http://www.nhsbsa.nhs.uk/Documents/PrescriptionServices/Information_Services_-_Issue_16_(Final)_2_07_2014.pdf)
36. NHS Business Service Authority. Volume and Cost of Special Order Products. Accessed 22/04/2016. Available online at: www.nhsbsa.nhs.uk/PrescriptionServices/3201.aspx

Additional PrescQIPP resources



Data pack

Available here: <https://www.prescqipp.info/resources/category/326-spot-list>

Information compiled by Sarah Clarke, PrescQIPP Programme, August 2016 and reviewed by Katie Taylor, Senior Medicines Evidence Reviewer, September 2016.

Non-subscriber publication January 2017.

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