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Medicines Optimisation

A guide for prescribers:
Special Order Pharmaceutical Products

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1. Purpose

The purpose of this guide is to provide health care professionals with a tool regarding the responsibilities attached to the prescribing, obtaining and administering special order medicines and the management of internal feeding tubes.

1.1. Background

Certain drugs are currently only available as specials; others may not be suitable for the patient requiring them, therefore prescribers in both primary and secondary care may need to consider prescribing an alternative form or dose of a medication that may not be commercially available (special order medicine) to ensure the patient takes their medicine safely and effectively. Medicine Optimisation teams are often asked for their input and advice regarding suitable alternatives when prescribers are considering the use of a special, these requests are becoming more frequent and complex.

Licenced products should be selected as first choice where suitable.

1.2. Key points

Question and Answer UKMI DOCUMENT – Follow the link to access
"What are the therapeutic options for patients unable to take solid oral dosage forms?"

https://www.sps.nhs.uk/wp-content/uploads/2013/09/NW_QA294_3_Solidoraldosageformsalternatives.doc

The UKMI document reflects the decision making process in 3 stages;

1. **Licensed medicines administered as intended**
2. **Licensed medicines administered in an unlicensed manner**
3. **Special-order products**

2. Specials:

2.1. Establish a clinical need

Prescribers should be vigilant when prescribing a special, or asking another professional to administer one. In general, specials should only be prescribed when the patient has an individual clinical need which cannot be met by a licensed medicine of established efficacy, quality and stability.

- Is an alternative formulation essential for this patient?
- Is there a licensed preparation which could meet the patient's needs, for example soluble tablets, liquid formulations, or patches?
- What are the unlicensed alternatives?
- Is local guidance available?

2.2. Identify medicines and preparations

The risks and benefits of using a special will change for individual patient groups. Prescribers need to take into account the safety, effectiveness, quality and cost effectiveness of all the options available to patients.

- What is the rationale for using an unlicensed medicine?
- Is there evidence or accepted practice to support usage?
- Is the dose critical?
- Is the patient a child?
- Does the medicine have a narrow therapeutic window?
- Is there a requirement to specify the exact formulation?
- What is the best value-for-money?
- Is there any local guidance?

2.3. Make a shared decision with the patient or carer

It is advisable that prescribers discuss treatment options with patients and carers to ensure that they are aware of the implications and practicalities of each option.

- What are the practical implications of prescribing?
- What is the shelf-life?
- How often will prescriptions be needed?
- How long does it take to obtain?
- Will the patient be taking the medicine themselves or will it be administered?
- Are there any implications for the choice of product?

2.4. Ensure prescribing governance

Prescribers should understand the rationale for using a special and the practical implications of prescribing before initiating, transferring, or taking over responsibility for prescribing.

- If initiating prescribing, how long is the patient expected to need this medicine?
- If asking someone to continue prescribing, are communications with the new prescriber optimised?
- If continuing the prescribing of a special, do prescribers know the formulation and source of the initial supply?
- Is there a need to ensure consistency of dose by specifying the formulation?

2.5. Ensure ongoing monitoring and review

Prescribers should have systems in place to ensure the need for the special is regularly reviewed, both in terms of the continued need for a special product and in the context of the need for a medicine overall.

- How often will the patient be reviewed?
- Who will do the review?

2.6. Guidelines for Good Practice and points to consider.

A link is included below to the Derbyshire Medicines Management Guidelines for Good Practice for reference and points to consider at the link below:

http://www.derbyshiremedicinesmanagement.nhs.uk/Specials

2.7. Dermatological Specials:

There are very few dermatological specials products listed, it is expected that combinations that appear on the British Association of Dermatologist (BAD) list would be used as first choice; http://www.bad.org.uk/shared/get-file.ashx?itemtype=document&id=1848 it is preferable that when prescribing a dermatological special consideration of the appropriateness of the product against the application of two individual products is taken into account. Dermatological specials are often difficult to track on Electronic Prescribing Analysis and Cost (ePACT).

2.8. Formulation:

Medicines may not be available in a formulation or dose suitable for the patient, there may be a need to change the formulation or dose suit the need of a patient e.g.; children, patients with swallowing difficulties or patients who have their medication administered via enteral feeding tube.

2.9. Liability

A licensed medicine that has been altered is no longer guaranteed by its licence the specials manufacturer is not responsible for any adverse event or treatment failure. The professionals who prescribe, supply and administer these medicines would be liable for any adverse event that the patient experiences.

It is therefore advisable for all professionals to check with their insurers that they are covered for prescribing, supplying or administering unlicensed medicines. Quoting CCG guidance does not absolve an individual from the responsibility of unlicensed medicines or the use of licensed medicines in an unlicensed manner.

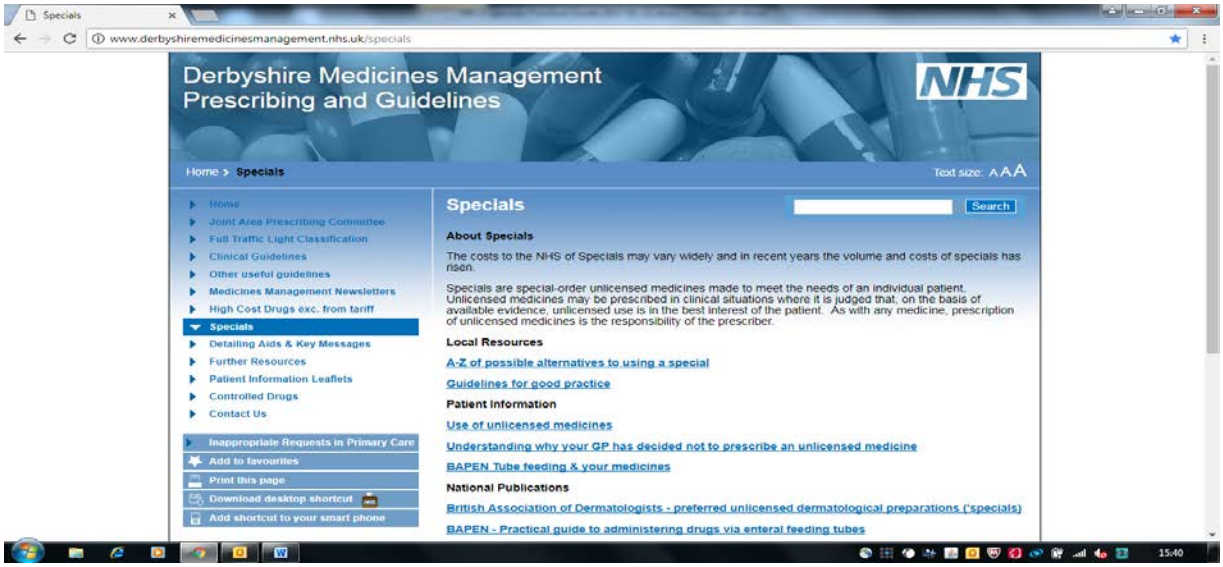
2.10 Patients with swallowing difficulties and or enteral feeding tubes:

It is important to ensure that oral medication required by patients who cannot take medication orally e.g. Patients with swallowing difficulties and or Patients who have their medication administered via an enteral feeding that alternative (licensed) routes of administration are sought first. If an alternative is not available unlicensed medicines may be prescribed either by instructing the patient to take the medicine in an unlicensed manner e.g. crushing a tablet or the use of a “special” order liquid.

There are five guidance principles to consider before prescribing an unlicensed medicine:

- Clinical need
- Available medicines and products (safety, effectiveness, quality and cost of all the options)
- Shared decision (with patient/carer what options are available)
- Prescribing Governance (particularly around transfer of responsibility)
- Monitoring and Review

2.11. Derbyshire Medicines Management Specials prescribing online portal.



The following link provides access to an A-Z list of possible alternatives when prescribing a special.

http://www.derbyshiremedicinesmanagement.nhs.uk/specials

The Derbyshire Medicines Management Specials Online Portal provides guidance on:

- Alternative licensed preparations exist.
- Tablets or capsule contents that can be crushed or dispersed in water (unlicensed route of administration).
- Injections that can be given orally / enterally (unlicensed route of administration).
- Specials products have been included in the specials tariff – Note, these are still unlicensed and

2.12. Prescribing alternatives (licensed/unlicensed)

When prescribing alternatives (licensed/ unlicensed) it is important to consider:

- Dose adjustments that need to be made with alternative liquid / injection preparations.
- Full dose directions need to be included on the prescription (if applicable) e.g. 'Disperse one tablet in water and take in the morning'.

If a medicine is not listed in The Derbyshire Medicines Management Specials Online Portal it may be necessary to prescribe a 'special' product – in this case the prescriber should consider the following:

- It is the prescriber's responsibility to decide whether the patient has 'special needs' which a licensed product cannot meet.
- They are prescribing an unlicensed medicine.
- That they are directly responsible for the prescribing of these products and that they may be liable for adverse effects or harm resulting from the use of that product.
- That the product, even though prepared in a manufacturing unit, has not been assessed by the Licensing Authority for safety, quality and efficacy (therefore still unlicensed).

Requests to prescribe unlicensed specials by a third party, e.g. secondary care, do not diminish the responsibility of the prescriber.

3. Prescribing Specials: MHRA Risk Hierarchy for the use of unlicensed medicines

3.1. Risk Hierarchy for the use of unlicensed medicines

- An unlicensed product should not be used where a product available and licensed within the UK could be used to meet the patient's special need.
- Although the MHRA does not recommend "off label" (outside of the licensed indications) use of products, if the UK licensed product can meet the clinical need, even "off-label", it should be used in preference to an unlicensed product. 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 a better risk position than in 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.
- If the UK product cannot meet the special need, then another (imported) medicinal product should be considered, which is licensed in the country of origin.
- If none of these options will suffice, then a completely unlicensed product may have to be used which would be produced by an appropriate Pharmaceutical specials manufacturer.
- The least acceptable products are those that are unlicensed in the country of origin, and which are not classed as medicines in the country of origin (but are in the UK). Hence, for example, the use of melatonin products from the USA,

where melatonin products are classed as supplements, not pharmaceuticals and may not be made to expected standards of pharmaceutical GMP should be avoided whenever possible.

4. Community Pharmacists

The Pharmacists' Defence Association (PDA) has stated that 'Pharmacists have a clear duty of care towards patients: should any problems arise members would need to demonstrate that any decisions taken had the patient's best interests in mind. Citing CCG recommendations or the prescriber's directions as a defence, would not absolve a pharmacist from their own personal professional responsibility towards patient care. The PDA recognises that there will be times where pharmacists acting in their patients best interests may need to consider supplying a medicine in a manner or form which interferes with the integrity of its license; such decisions should only be taken after following a considered professional cognitive process. In so doing and despite going through such a process, the pharmacist will be taking a personal risk and in the event that something goes wrong, they will be held to account for their actions. The PDA would like to give reassurances to its members that where pharmacists act in a responsible and professional manner and decide to make such a supply, the underwriters will continue to provide cover should a problem arise".

5. Specials Tariff

Since November 2011 there has been in place a specific specials tariff of frequently ordered special products which can be accessed via the following link:

http://www.nhsbsa.nhs.uk/PrescriptionServices/3754.aspx

The specials tariff is updated quarterly. The prescriber should consult the tariff for the most cost effective formulation and quantity to request.

Please note:

Every effort has been made to ensure the information in this document is current and correct; however information regarding individual drugs may change. It is therefore advisable that dose information is always checked against manufacturers' recommendations, published literature or other specialist sources.

6. Feeding Tubes - general guidelines

Administering drugs via feeding tubes is an unlicensed activity. Recommendations are theoretical and/or based on local policy. An alternative ***licensed option*** is always preferable e.g. rectal or parenteral formulations.

6.1. Types of Feeding Tubes

There are several types of feeding tubes. (***N.B.*** These can be further classified according to lumen size, number of lumen and length of use).

Type of Tube	Site
NG - Nasogastric	Inserted into the stomach via the nose
NJ - Nasojejunal	Inserted into the jejunum via the nose
PEG - Percutaneous endoscopic gastrostomy	Inserted into the stomach via the abdominal wall
PEJ - Percutaneous endoscopic jejunostomy	Inserted into the jejunum via the abdominal wall
PEGJ - Percutaneous endoscopic gastrojejunostomy	Inserted into the jejunum via the abdominal wall and through the stomach

6.2. General Guidelines for Administration

The following should be considered when giving medicines via feeding tubes:

- Ensure route of administration has been specified
- Ensure the siting of the tube has been medically confirmed
- Oral syringes (i.e. a syringe to which a needle cannot be attached) should be used to prevent accidental parenteral administration
- Stop the infusion of a feed when administering medicines.
  Refer to *section 5.4 of this guidance: Drug interactions* for further guidance
- Flush the tube slowly with at least 15ml of water (sterile water if jejunal tube) using either a 30ml or 50ml oral syringe
- Administer each medicine separately (by gravity flow) as a sediment free liquid. Flush in between and afterwards with at least 15ml of water (sterile water if jejunal tube) using either a 30ml or 50ml oral syringe.
- Monitor clinical response if
    - Changing from modified release to normal release preparations
    - A drug has a narrow therapeutic index
    - The bio-availability of the drug differs between tablet and liquid.
- Do not administer bulk-forming laxatives because they block the tubes; use an enteral feed with a high-fibre content instead
- Do not add medicines to feeds; this increases the risk of incompatibility, microbial contamination, tube blockage and underdosing or overdosing if the feed rate is altered.
- Narrow lumen tubes are more likely to block, particularly with thick oral syrups; dilute with 30-60mL of water before administration.

- Ensure correct lumen is used with multilumen tubes; do not use an aspiration gastric decompression port for drug administration.
- Medicines should not be administered by tube if it is on free-drainage or suction

6.3. Choosing a Suitable Formulation

Commercially available oral solutions/suspensions/syrups are not always suitable for administration into feeding tubes because:

Problem	Reason	Preventive measures that can be taken
Osmotic diarrhoea	Due to high osmolarity and sorbitol content	Osmolarity can be reduced in some preparations by diluting with as much water as practical.
Altered bioavailability and/or pharmacokinetics	When converting from tablets to oral solution, e.g. digoxin and phenytoin or from modified release preparations to oral solution.	The dose and/or frequency may need to be changed according to clinical response
Tube blockage/caking	Caused by high viscosity preparations e.g. co-amoxiclav	Minimise by diluting with 30-60mL water or use suspensions rather than syrups.
Clumping of the feed	Particularly if the formulation is acidic, i.e. pH<4	Find alternative route/ preparation if possible Dilute the drug as much as possible to minimise drug-feed contact and flush with 30-60mL of water
Binding to the Plastic Tubing	e.g. Carbamazepine, clonazepam, diazepam, Phenytoin	Dilute the drug with at least 30-60mL water and flush well.

6.3.1. Tablets/capsules

- Tablets and the contents of many capsules will disperse completely when crushed and mixed with water, even when they are not marketed as dispersible.
- Do not administer crushed tablets or the contents of capsules which have not completely dispersed in water; sediment increases the risk of blocking the tube.
- The liquid contents of some capsules can be drawn out with a syringe, but should be administered immediately in case of light sensitivity.

6.3.2. Injections

An expensive option and should be considered for short term administration only. Before administering an injectable formulation via a feeding tube: check

- Osmolarity;- many injections are hypertonic and unsuitable.
- Does the injection contain additives unsuitable for oral administration. *e.g.* polyethylene glycol in amiodarone.

All injections should be further diluted with 30-60ml water before administration.

6.4. Drug Interactions

A number of specific drug interactions can occur when medicines are administered via feeding tubes. The most important clinically are in connection with drugs that have a narrow therapeutic range such as digoxin, phenytoin or warfarin.

Interaction	Preventative Measure
Drug/enteral feed incompatibilities affecting drug absorption *e.g. carbamazepine, ciprofloxacin, hydralazine, phenytoin, theophylline, warfarin*	Stop the feed for one hour before and one to two hours after administrating the drug *(for phenytoin two hours before and after).* Dilute the drug as much as possible, and flush with 30-60mL of water.
Drugs requiring administration on an empty stomach *e.g. penicillins, ketoconazole, tetracyclines.*	Balance risk of reduced absorption against practicality of stopping feed for one hour before and after each dose. Consider alternative route/drug.
Drug-feed indirect interaction *e.g. Warfarin and vitamin K in feed.*	Monitor INR and adjust anticoagulant dose if necessary
Drug-drug direct interaction *e.g. iron or zinc and ciprofloxacin*	Alter drug timings

6.5. Unblocking Tubes

For advice on unblocking tubes, please refer to your nurse specialist.

NOTE: Do not use guidewire to unblock tubes as there is a danger of perforation. Acidic solutions *e.g.* cranberry juice and carbonated drinks could make the situation worse by causing feed coagulation.

7. Prescribing Lactose free and Gluten free medicines

Prescribers may be asked to supply medicines for patients with a lactose or gluten allergy / intolerance.

Lactose free:

UKMi have produced a Q&A sheet which prescribers may find useful when asked to prescribe Lactose free medication, this can be found at:

https://www.sps.nhs.uk/articles/what-factors-need-to-be-considered-when-prescribing-for-lactose-intolerant-adults-2/

A basic guide produced by the NHS on lactose intolerance can be found at:

https://www.nhs.uk/conditions/lactose-intolerance/

Gluten free:

UKMi have also produced a Q&A sheet which prescribers may find useful when asked to prescribe Gluten free medication, this can be found at:

https://www.sps.nhs.uk/articles/what-is-the-gluten-content-of-oral-prescription-medicines/

A basic guide to Coeliac disease produced by the NHS can be found at:

https://www.nhs.uk/conditions/coeliac-disease/

8. UKMI North West Academic Detailing Aid

Choosing medicines for patients unable to take solid oral dosage forms

Selecting suitable formulations for adult patients with swallowing difficulties or feeding tubes

A stepped approach is suggested:

STEP 1

Use a licensed medicine in a suitable formulation.

For example:
- Licensed liquid preparation
- Soluble tablets
- Powders or granules for suspension

In order to use a licensed medicine, consider switching to a different agent in the same class, or to a different route of administration.

For example, consider:
- Fluoxetine liquid (licensed preparation) as an alternative to sertraline tablets,
- Aspirin dispersible tablets instead of clopidogrel tablets,
- HRT patches instead of tablets.

Consider the patient's method of feeding:

Patients on liquid feeds may take oral liquid medicines, dispersible tablets or solid preparations dispersed in water. For patients on thickened fluids, liquid medicines can be mixed with products like *Thick and Easy*.

Patients on soft-food diets may be able to swallow crushed tablets or the contents of capsules given with food.

Patients with enteral feeding tubes may have oral medicines given by this route.

Why licensed status matters

To be granted a licence a medicine must meet quality standards and be shown to be safe and effective. Licensed medicines usually come with a patient information leaflet and are considered the safest choice.

Special-order medicines are unlicensed and are not required to meet the same standards as licensed medicines. Prescribers take greater responsibility when using them.

STEP 2

Consider using a licensed medicine in an unlicensed manner, for example by dispersing tablets in water or by opening capsules.

For example:
- Clindamycin capsules can be opened and the contents mixed with water.
- Bendroflumethiazide tablets can be dispersed in water.
- Both examples are suitable for administration orally or via a feeding tube.

Not all medicines are suitable for administration in this way and it is important to check beforehand. See over for where to get advice.

As before, consider switching to a different agent or route of administration in order to use a licensed product.

Is it needed?

If the patient is taking medicines that aren't needed or aren't working, stop or change them.

Care staff should only give licensed medicines in an unlicensed way if there is a written direction in the patient's care plan.

Practical directions are overleaf.

In many cases a licensed preparation will be available that meets the patient's needs.

Cost

Special-order medicines are often considerably more expensive than licensed medicines. They may have short shelf-lives compared to licensed alternatives and may need fridge storage.

For example, bendroflumethiazide liquid is 80 times more expensive than tablets:
- 28 doses of 2.5mg tablets costs about £1,
- 30 doses of 2.5mg/5ml liquid (150ml) costs more than £80.

Bendroflumethiazide tablets can be dispersed in water for administration orally or via feeding tubes.

STEP 3

In situations where there is no suitable licensed option, consider using a 'special'.

Special-order ('special') liquid medicines are unlicensed and expensive. They should only be prescribed if there is no licensed medicine that meets the patient's needs.

Licensed medicines should be used where possible.
Special-order medicines are unlicensed and expensive and should only be prescribed if necessary.

Practical directions

Always check beforehand if a tablet is suitable for dispersing or crushing, or if a capsule is suitable for opening.

- **Crushing or dispersing tablets**

Many immediate-release tablets can be dispersed in water without crushing; some medicines need to be crushed first. Some tablets (e.g. modified-release) are not suitable for crushing.

For medicines that are suitable for crushing, crush using a tablet crusher, a pestle and mortar or between two metal spoons.

Only crush medicines one at a time; do not crush all the patient's medicines together. Crushing or dispersing should only be performed immediately before administration.

- **Opening capsules**

Some hard gelatin capsules can be opened and their contents mixed with water or administered with food. Some capsules are too small to manipulate. Capsules should only be opened immediately before administration.

- **Giving medicines in liquids or soft food**

Some capsule contents or crushed tablets can be given with a small amount of cold liquid or cold soft food such as a teaspoon of yoghurt or jam. Use a small amount of food to ensure the full dose is taken; if taken with a meal, add medicine to the first mouthful of food.

Crushed tablets or capsule contents may taste very bitter to patients taking them orally. Mask the taste by giving with strong flavours such as blackcurrant.

Medicines should only be administered in food with the patient's knowledge and consent. Hiding medicines in food is considered 'covert administration' and is only condoned in certain circumstances.

- **Giving medicines via feeding tubes**

Feeding tubes should be flushed with water before and after each medicine is administered. If a liquid medicine is thick or syrupy, dilution may be required. Some patients are fluid restricted and that needs to be taken into account.

When administering crushed tablets or opened capsules via a feeding tube, add the powder to 15-30ml water and mix well. Draw into a 50ml oral syringe and administer. If you have used a mortar or tablet crusher, rinse this with water and administer the rinsings also.

Suggested protocol for administering medicines via feeding tubes:

1. Stop the feed (leaving a feeding break if necessary).
2. Flush the tube with 30ml water.
3. Prepare the first medicine for administration, and give it.
4. Flush with 10ml water.
5. Repeat stages 3 and 4 with subsequent medicines.
6. Flush with at least 30ml water.
7. Re-start the feeding (leaving a feeding break if necessary).

Care staff may only administer medicines in an unlicensed manner on the instruction of the prescriber.
A written direction to crush or disperse tablets or to open capsules should be documented in the patient's care plan.

Where can I get advice?

- **Medicines management and medicines information pharmacists**

For advice on choosing appropriate dosage forms or to check if tablets or capsules can be dispersed, crushed or opened and dispersed, contact your medicines management team or UKMi medicines information centre.

Contact details for UKMi medicines information centres are available at www.ukmi.nhs.uk. Click on the map then search for your local or regional centre.

- **Medicines Q&A**

This leaflet accompanies a *Medicines Q&A* document which provides further information and lists options available in several therapeutic areas for adult patients with swallowing difficulties or feeding tubes. Access it online via the link at the bottom of the page.

- **Reference sources**

Details of two respected texts and websites are at the bottom of the page.

Only prescribe special-order medicines if there is no suitable licensed medicine available that meets the patient's needs.

It may be appropriate to use a licensed medicine in an unlicensed way.

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10. Acknowledgements

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Cambridge and Peterborough NHS Foundation Trust

Appendix One: Abbreviations

Abbreviation	Definitions
BAD	British Association of Dermatologist
ePACT	Electronic Prescribing Analysis and Cost
PDA	Pharmacists' Defence Association
TIA	Transient ischaemic attack
MHRA	Medicines and Healthcare products Regulatory Agency
GMP	Good Manufacturing Practice