MINOR AILMENTS SERVICE

FORMULARY

February 2008

for use in community pharmacy

CONTENTS PAGE

B – prescribe and dispense (endorse) by brand G – reimbursed generic cost (part 7 DT), prescribe and dispense generically
b – one or more brand/manufacturer available can prescribe generically, but dispense (and endorse) by brand/manufacturer

INTRODUCTION

Welcome to the new version of the Tayside Minor Ailment Scheme formulary. Each section details the medication including suggested quantity to prescribe for guidance. We have also included good practice points, counselling points and when to refer a patient to their GP as appropriate.

Against each medication we have used a key (denoted by G, B or b) to encourage cost effective prescribing, whilst ensuring that you will be reimbursed correctly. The key is as follows –

G reimbursed generic cost (listed in part 7 DT), prescribe and dispense generically, any brand or manufacturers endorsement will be ignored, will be paid from pack size detailed
B prescribe and dispense (endorse) by brand to ensure reimbursement
b one or more brand or manufacturer available, can prescribe generically, but suggested dispense (and endorse) by brand or manufacturer to ensure reimbursement

We have also identified any medications which are licensed for use in younger children with this icon , but please refer to product licence details.

Any changes or updates will be made to this formulary electronically and new version posted in the MAS section of the Tayside Area Prescribing Guide. For the most up-to-date version of this document review electronically. Where a statement is made after a medicine (e.g. in section 1.1 of TAPG) this identifies that the medicine has a main entry within the Tayside Area Prescribing Guide (TAPG). However dosage directions within the TAPG may not apply to medicines supplied OTC with MAS.

Pricing Guide and Pricing Rules

Following agreement with Community Pharmacy Scotland, PSD implemented new pricing procedures from 1 September 2007. CPS produced a really useful document detailing these 'rules' which we have reproduced here:

All MAS prescriptions are now priced using the rules in place for the pricing of GP10 prescriptions. The main impact for you will be on the pricing of prescriptions for items where a version of that product appears in Part 7 of the tariff.

The MAS specification sets out the formulary available to you:

- all P and GSL medicines which are not blacklisted,
- dressings and appliances from Part 2 of the tariff,
- selected items from Part 3 of the tariff,
- any Prescription Only Medicines agreed suitable and which are underpinned by PGDs.

This is then qualified by the statement that you should prescribe in line with local and national NHS prescribing policy and guidance such as local MAS formularies (such as this one).

In order to ensure that payment will be made for medicines prescribed under MAS, you need to pay special attention to the prescribing of those items which are available in both counter and dispensing packs (i.e. as P, GSL and POM products). Examples are aciclovir cream or mebeverine tablets. The majority of items in Part 7 are held on file as POM packs and that is the default option which will be used for pricing. We have introduced a number of smaller P packs into the tariff and we will continue to work on adding more as necessary, but we have now been able to identify a number of products where that solution is not available to us. The only option left is to prescribe using the proprietary name for the product and for payment to be made on that basis. However as payment should have been made for that product anyway it should not generate additional cost to the NHS.

We have subdivided this guide into 5 sections:

- **Part A** consists of those items in Part 7 which you can prescribe generically and expect payment to be made at the tariff rate. Only pack size endorsements will be considered for these products.
- **Part B** consists of the items in Part 7 where we would advise you to prescribe a non black-listed proprietary product in order to secure payment.
- **Part C** contains the items currently allowed on MAS scripts from Part 2 and 3 of the Drug Tariff
- **Part D** contains information on the National PGDs currently in operation.
- **Part E** contains details of items, not in the Drug Tariff, which are commonly disallowed.

Part A MAS formulary medicines with a version in Part 7 which you can prescribe generically and expect to be paid at the DT rate.

- You can prescribe generically
- You should endorse the pack size when more than one pack size is listed in the DT.
- You will be paid at the DT rate
- Any other endorsement will be ignored

Generic	Form	Strength	Smallest DT Pack
Aciclovir	Cream	5%	2g
Aqueous Cream	Cream		100g*
Aqueous Cream	Cream		500g*
Aspirin Dispersible	Tabs	300mg	32
Bisacodyl	Tabs	5mg	1000
Calamine	Lotion		200ml
Calamine Aqueous	Cream		100g
Cetirizine	Tabs	10mg	30
Cetirizine Oral	Solution	5mg/5ml	200ml
Chloramphenicol	Eye Drops	0.50%	10ml
Chlorphenamine	Tabs	4mg	28
Clotrimazole	Cream	1%	20g
Co-Codamol	Tabs	8/500mg	32
Emulsifying	Ointment		500g
Fluconazole	Capsules	150mg	1
Glycerin Adult	Suppositories	4g	12
Glycerin Child	Suppositories	2g	12
Glycerin Infant	Suppositories	1g	12
Hydrocortisone	Cream	1%	15g
Hydrocortisone	Ointment	1%	15g
Hypromellose	Eye Drops	0.30%	10ml
Ibuprofen	Tabs	200mg	24
Ibuprofen	Tabs	400mg	24
Ibuprofen	SF Suspension	100mg/5ml	100ml
Lactulose	Solution		300ml*
Lactulose	Soln		500ml*
Menthol	Crystals		5g
Olive Oil	Oil		2000ml
Paracetamol	Tabs	500mg	32
Paracetamol	Suspension	250mg/5ml	500ml
Paracetamol	SF Suspension	120mg/5ml	100ml
Paracetamol	SF Suspension	120mg/5ml	200ml
Paracetamol	SF Suspension	250mg/5ml	200ml
Paracetamol Soluble	Soluble Tabs	500mg	60
Pholcodine	Linctus	5mg/5ml	200ml

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Pholcodine SF	Linctus	5mg/5ml	2000ml
Senna	Tabs	7.5mg	60
Simple Linctus	Linctus		200ml
Xylometazoline	NasalDrops	0.10%	10ml
Xylometazoline	NasalSpray	0.10%	10ml
Xylometazoline Paed	NasalDrops	0.05%	10ml

Part B MAS formulary medicines with a version in Part 7 where we would advise you to prescribe a non Blacklisted proprietary product in order to secure payment

- The DT packs shown in the table below are POM packs even though there are P packs available.
- PSD uses these DT packs for pricing as they are the only packs held onfile for these generics.
- You cannot prescribe POM packs (unless there is a PGD in place)
- Prescribe a non black-listed proprietary product.

Generic	Form	Strength	Tariff pack
Beclomethasone	Nasal Spray		200 dose
Bisacodyl	Tabs EC	5mg	12
Clotrimazole	VaginalTabs	500mg	1
Domperidone	Tabs	10mg	30
Ketoconazole Shampoo(for seborrhoeic dermatitis of scalp)			120ml
Ketoprofen	Gel	2.50%	100g
Loperamide	Caps	2mg	30
Loratadine	Tabs	10mg	30
Loratadine	Syrup	5mg/5ml	100ml
Mebeverine	Tabs	135mg	100
Omeprazole	Tabs	10mg	28
Sodium Cromoglycate	Eye Drops	2%	13.5ml
Sumatriptan	Tabs	50mg	6

Part C Items Prescribable under MAS from Parts 2 and 3 of the Drug Tariff

Part 2 Dressings

Pharmacists may prescribe all products in Part 2 of the Drug Tariff, other than those marked as GP10a only. Refer to the NHS Tayside Wound Management Formulary for further information on dressing selection. Click here

Part 3 Appliances

- The following appliances are the only ones **allowed** on a MAS prescription form:
- Bug Buster Head Lice detection and eradication kit
- Nitty Gritty Nit Comb
- Sodium Chloride (saline) nasal drops 10ml
- Sodium Bicarbonate Ear Drops 10ml
- Saliva preparations

Part D Prescription Only Medicines (POMs) underpinned by national Patient Group Direction (PGDs) for MAS.

Currently there are three in use:

- Chloramphenicol Eye Drops 10ml (POM)
- Fluconazole 150mg Capsules (Pack size of 1) (POM)
- Miconazole cream 2% 30g (P)

These PGD's are attached as appendices.

Part E Commonly Disallowed Items – non Drug Tariff

The latest full list of blacklisted medicines can be found on the CPS website at - www.communitypharmacyscotland.org.uk/_resources/files/Contractor%20Services/BLACKLIST.pdf

ITEM WHICH HAS BEEN DISALLOWED	REASON FOR DISALLOWING	ALLOWED ITEM
Adcortyl in Orabase paste 5g	The words 'mouth ulcer' have been omitted	Adcortyl in Orabase mouth ulcer paste 5g
Aluminium Hydroxide SF susp	No mention of SF formulation in any price list.	Aluminium Hydroxide suspension
Anusol HC ointment	Anusol HC Ointment is a POM, Anusol Plus HC is the P pack	Anusol Plus HC ointment
Anusol HC suppositories	Anusol HC suppositories are a POM. Anusol Plus HC suppositories are the P pack	Anusol Plus HC supps
Clobetasone cream 0.05% 30g	30g pack is a POM	15g pack
Daktacort cream	The term HC which is the P pack has been omitted	Daktacort HC cream
Emergency Hormonal Contraception Products (EHC)	Not allowed under MAS	None
Ibuprofen syrup	Syrup = Brufen which is a POM	Ibuprofen suspension
Ketoprofen gel 2.5% 30g	Unless the 30g P pack is clearly endorsed, pricing defaults to the DT 100g POM pack.	Ketoprofen gel 2.5% 30g P pack (A branded product)
Liquid Paraffin/White soft Paraffin (Loveridge)	Version is not held on file by PSD	Liquid Paraffin/White soft Paraffin
Mebendazole chewable tabs ('Own brand')	This is a price file problem. Own brands tend not to be on PSD's file.	A branded P product
Mebendazole suspension 30ml	The Janssen product is a POM.	A branded P product
Motilium tabs 10mg	Must be prescribed specifically as the P licensed pack. Motilium without a number 10 in the title is a POM	Motilium 10 tabs 10mg
Nicotine Replacement Therapy Products (NRT)	Not allowed under MAS	None
Paracetamol caplets 500mg 32	The version held on file is a POM	Tablets or capsules
Terbinafine cream 15g	POM quantity prescribed	A branded 7.5g P pack
Terbinafine cream 30g	POM pack prescribed	A branded 7.5g P pack

USEFUL CONTACTS

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For all ePharmacy Minor Ailments Service (MAS) enquiries, contact Practitioner Services Department (PSD) on 0131 275 6600.

For all technical enquiries, please contact your PMR supplier.

Community Pharmacy website - www.communitypharmacy.scot.nhs.uk

GASTROINTESTINAL SYSTEM

DYSPEPSIA AND GASTRO-OESOPHAGEAL REFLUX

Compound alginates and proprietary indigestion preparations BNF section 1.1			
Co-magaldrox SF suspension 195/220	(in section 1.1 of TAPG)	500ml	b
Gaviscon® Advance suspension		up to 500ml	b
Gaviscon® Advance tablets		60	b
Drugs used in nausea and vertigo BNF section 4.6			
Motilium® 10 tablets (Domperidone)	(in section 4.6 of TAPG)	10	B
Ulcer healing drugs			
H2-receptor antagonists BNF section 1.3.1			
Ranitidine 75mg tablets	(in section 1.3 of TAPG)	up to 24	B
Proton pump inhibitors BNF section 1.3.5			
Omeprazole 10mg tablets	(in section 1.3 of TAPG)	14	B

Good practice points
Patients with symptoms suggestive of underlying disease should be referred to their GP, e.g. patients complaining of progressive difficulty swallowing, progressive unintended weight loss or sudden onset of symptoms especially in middle age or elderly, coughing up blood, anaemia-like symptoms.
Normal lifestyle advice is necessary, e.g. weight loss, smoking, alcohol.
Liquid antacids are more effective than tablets.
Ranitidine and omeprazole should only be used short term. If problems persist, refer to GP.
Compound alginates preparations are less powerful antacids than co-magaldrox but may be more effective for heartburn.
Omeprazole – use RPGGB good practice guidance 'OTC omeprazole'

Examples of counselling points
Avoid large meals, eat little and often.
Do not rush your food.
Avoid spicy and greasy foods as they can often worsen heartburn.
Some heartburn remedies can stop other medicines form working. Check if the heartburn remedy would interfere with other medicines.

When to advise patient to contact their GP
Pain is severe or radiating
Blood in vomit or stools
Melaena stools
Symptoms are persistent (longer than 5 days) or recurrent
Pain worsens on effort
Persistent vomiting
Treatment has failed (no improvement in symptoms after 5 days).
Adverse drug reaction is suspected
Associated weight loss.

GRIPES/COLIC/WIND PAIN

Compound alginates and proprietary indigestion preparations BNF section 1.1

Gaviscon Infant Sachets	15x2g	b

Simethicone

Infacol	50ml	b

Examples of counselling points
If breastfeeding suggest mother avoids spicy foods, or try to find out which foods you are eating that may be excreted into the breast milk (as this may be aggravating baby (i.e. hypersensitivity to certain foods).
They may also recommend giving lots of cuddles when colic is absent in an attempt to reduce stress.

When to advise patient to contact their GP
Infant who fails to thrive.
Projectile vomiting
Clearly exhausted parents.

IRRITABLE BOWEL SYNDROME

Antispasmodics and other drugs altering gut motility BNF section 1.2

Mebeverine 135mg tablets	(in section 1.2 of TAPG)	15	B

When to advise patient to contact their GP
Children.
Older person with no previous history of IBS.
Pregnant women.
Blood in stools.
Unexplained Weight Loss.
Caution in patients aged over 45 with changed bowel habit.
Signs of bowel obstruction.
Unresponsive to appropriate treatment

ACUTE DIARRHOEA

First choice: oral rehydration salt sachets BNF section 9.2.1.2

Oral rehydration salt sachets	(in section 9.2 of TAPG)	up to 20	b

Second choice: Antimotility drugs BNF section 1.4.2

Loperamide 2mg capsules	(in section 1.4 of TAPG)	up to 12	B

Good practice points
First-line treatment of acute diarrhoea is rehydration therapy.
Patients with symptoms suggestive of underlying disease should be referred to their GP, e.g. blood in stools, major change in bowel habits especially in middle age or elderly.
Patients with chronic diarrhoea should be referred to their GP.

Examples of counselling points
The diarrhoea normally stops within 48-72 hours without treatment.
Replacement of fluids is of particular importance especially in children and the eldery.

When to advise patient to contact their GP
Adults and children >3 years: diarrhoea of duration of greater than 3 days.
Children 1-3 years: diarrhoea of duration of greater than 2 days.
Children < 1 year: diarrhoea of duration of greater than 1 day.
In severe cases referral should be recommended immediately.
Association with severe vomiting and fever.
Suspected drug-induced reaction to prescribed medication.
Presence of blood or mucus in stools.

CONSTIPATION

Bulk-forming laxatives BNF section 1.6.1			
Ispaghula Husk sachets	(in section 1.6 of TAPG)	10/30	b
Stimulant laxatives BNF section 1.6.2			
Bisacodyl tablets		20	G
Glycerin suppositories	(in section 1.6 of TAPG)	12	G
Senna 7.5mg/5ml liquid	(in section 1.6 of TAPG)	100ml	b
Senna 7.5mg tablets	(in section 1.6 of TAPG)	20	G
Osmotic laxatives BNF section 1.6.4			
Lactulose solution	(in section 1.6 of TAPG)	300ml/500ml	G

Good practice points
Investigation of reasons for constipation may lead to referral rather than a treatment under Minor Ailment Scheme. Patients with symptoms suggestive of underlying disease should be referred to their GP, e.g. blood in stools, unexplained weight loss, jaundice, passage of mucus in the stools, major change in bowel habit especially in middle age or elderly.
Normal counselling - advice on diet/exercise is necessary.
Use of laxative in children should be discouraged, referral to GP may be appropriate.

Examples of counselling points
Drink more fluids but no tea, coffee, cola or alcohol.
Eat more fibre found in wholemeal foods, fruit and fresh vegetables.
Regular exercise improves bowel habits.
Never put off going to the toilet when you know you need to go.
Ispaghula sachets should not be taken immediately before going to bed.
Lactulose may take up to 48 hours to act.

When to advise patient to contact their GP
Persistent change in bowel habit.
Presence of abdominal pain, vomiting, bloating.
Blood in stools.
Melaena stools.
Prescribed medication suspected of causing symptoms.
Failure of OTC medication (no relief of symptoms within 7 days).

HAEMORRHOIDS

Soothing haemorrhoidal preparations BNF section 1.7.1			
Anusol® cream	(in section 1.7 of TAPG)	23 g	b

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Anusol® ointment	(in section 1.7 of TAPG)	23 g	b
Anusol® suppositories	(in section 1.7 of TAPG)	12	b

Compound haemorrhoidal preparations with corticosteroids BNF section 1.7.2

Anusol Plus HC® ointment	(in section 1.7 of TAPG)	15 g	b
Anusol Plus HC® suppositories	(in section 1.7 of TAPG)	12	b

Good practice points
Patients with symptoms suggestive of underlying disease should be referred to their GP, e.g. profuse bleeding, blood that is dark, blood in the stools, extremely painful haemorrhoids, anaemia-like symptoms, change in bowel habit towards looser stools and/or increased stool frequency persisting 6 weeks or more (especially in middle age or elderly).
Patients should be advised to increase their fluid and fibre intake to avoid hard stools.
Good toilet hygiene is important.

Examples of counselling points
Increase your fluid intake, not tea, coffee, cola or alcohol.
Increase your fibre intake.
Take some form of regular exercise.
Do not strain when you go to the toilet – try to relax.
Treatment should no be for longer than 7 days with hydrocortisone products.

When to advise patient to contact their GP
Duration of longer than 3 weeks.
Change of bowel habit (persisting alteration from normal bowel habit).
Presence of blood in stools/melena
Suspected drug-induced constipation.
Associated abdominal pain/vomiting.

RESPIRATORY SYSTEM

ALLERGY

Antihistamines BNF section 3.4.1

Non sedating

Cetirizine 10mg tablets	(in section 3.4 of TAPG)	7	B
		30	G
Cetirizine oral solution 5mg/5ml	(in section 3.4 of TAPG)	70ml	B
		200ml	G
Loratidine 10mg tablets	(in section 3.4 of TAPG)	7	B
		30	B
Loratidine syrup 5mg/5ml	(in section 3.4 of TAPG)	100ml	B

Sedating

Chlorphenamine 4mg tablets	(in section 3.4 of TAPG)	30	G
Chlorphenamine oral solution 2mg/5ml	(in section 3.4 of TAPG)	150ml	b

Also see Nasal allergy and Eye - Other anti-inflammatory products

Good practice points
Patients complaining of wheezing, shortness of breath, or chest tightness should be referred to their GP.
Acute urticaria is usually self-limiting, and if mild, treatment is often unnecessary. Oral antihistamines are useful. Sedating oral antihistamines may be particularly helpful if sleep is disturbed.

Drowsiness is rare with non sedating antihistamines, however, patients should be advised that it can occur and may affect performance of skilled tasks and excess alcohol should be avoided.
Drowsiness is a significant side effect of sedating antihistamines.

Examples of counselling points
For hayfever, start taking before season starts and continue throughout.
Advise to go to GP for regular prescription if required.
Avoid going out when the pollen count is high.

When to advise patient to contact their GP
Wheezing or shortness of breath, tightness of chest.
Persisting painful ear or sinuses.
Purulent conjunctivitis.
Failed medication (no improvement in symptoms after 10 days).

COUGH

Cough preparations BNF section 3.9

	Simple SF linctus	200 ml	G
	Simple paediatric SF linctus	200 ml	G
	Pholcodine SF linctus	200 ml	G
	Pholcodine paediatric SF linctus	200 ml	b

Good practice points
Persistent cough along side other alarm symptoms, e.g. weight loss, fluid retention, wheezing, is a reason for referral to GP.
All recommended liquids should be sugar-free it at all possible.
Pholcodine linctus may be indicated for dry or painful cough if sleep is affected.

Examples of counselling points
Drink plenty of fluids.
Chesty coughs can last up to two weeks whilst dry coughs can continue for three to four weeks.
Smokers can suffer more with their coughs, advice can be given on smoking cessation.

When to advise patient to contact their GP
Cough lasting 2 weeks or more.
Sputum yellow, green, rusty or blood stained.
Chest pain.
Shortness of breath.
Wheezing.
Whooping cough or croup.
Recurrent nocturnal cough.
Suspected adverse drug reaction (e.g. ACE inhibitors).
Failed medication (no improvement in symptoms after 5 days).

NASAL CONGESTION

Aromatic inhalations BNF section 3.8

	Menthol crystals	5 g	G

Systemic nasal decongestants BNF section 3.10

	Pseudoephedrine 60mg tablets	12	b
	Pseudoephedrine 30mg/5ml elixir	100ml	b

Also see Topical Nasal decongestants

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Good practice points
Pseudoephedrine sales should be limited to one packet per transaction with a maximum of 12x60mg or equivalent.
Systemic decongestants provide short-term relief of congestive symptoms (3-10 hours).
Ensure correct directions for use are given and that awareness is raised over the dangers of using boiling water.

Examples of counselling points
Inhalation of warm moist air can be useful in the management of symptoms.

CENTRAL NERVOUS SYSTEM

ANALGESICS AND ANTIPYRETICS

Non opioid analgesics BNF section 4.7.1

Paracetamol 500mg tablets	(in section 4.7 of TAPG)	32	G
Paracetamol soluble 500mg tablets	(in section 4.7 of TAPG)	60	G
Paracetamol oral suspension SF 120mg/5ml	(in section 4.7 of TAPG)	100/200ml	G
Paracetamol oral suspension SF 250mg/5ml	(in section 4.7 of TAPG)	100/200ml	G

Weak opioids BNF section 4.7.1

Co-codamol 8/500 mg tablets		32	G
Co-codamol dispersible 8/500 mg tablets		Up to 32	b

Also see non-steroidal anti-inflammatory drugs within musculoskeletal

Good practice points
There is significant potential for accidental overdose. Prescribers should be aware of other analgesic preparations (prescribed, over the counter or 'borrowed') that patients may be taking.
Paracetamol is preferable to ibuprofen in the elderly.
Compound analgesic containing an opioid may produce opioid side-effects and can complicate treatment of overdose.
Co-codamol 8/500mg tablets are no more effective than paracetamol.

Examples of counselling points
Rest should be taken to allow the injury to recover.
Cold packs should be applied to reduce swelling and bruising.
The area should be elevated if possible to remove fluid from area of injury.

When to advise patient to contact their GP
Headache associated with injury/trauma.
Sudden onset servere headache
Severe headache of more than 4 hours duration.
Suspected adverse drug reaction.
Headache in children under 12 years old.
Severe occipital headache (across the back of the head).
Headache is worse in the mornings and then improves.
Associated drowsiness, visual distrubances or vomiting.
Neck stiffness.

MIGRAINE AND ASSOCIATED SYMPTOMS

Patients should have a confirmed diagnosis of migraine before OTC supply.

Analgesics BNF section 4.7.4.1			
Migraleve® complete		12/24/48	b
Anti-emetics BNF section 4.6			
Buccastem M® 3mg tablets	(in section 4.6 of TAPG)	8	b
5HT1 Agonists BNF section 4.7.4.1			
Imigran Recovery® 50mg tablets	(in section 4.7 of TAPG)	2	B

Good practice points
First –line treatment should be simple analgesic, with an anti-emetic if necessary. Second-line – Imigran Recovery®.
Complete Migraine Questionnaire to determine whether Imigran Recovery is an appropriate for patient – contraindications and interactions.
Sumitiptan - use RPSGB - good practice guidance 'OTC sumitiptan'.

When to advise patient to contact their GP
Patients on the combined contraceptive pill.
Pregnant or breastfeeding patients.
Patients with persistent migraine.
Hypersensitive patients.

MUSCULOSKELETAL AND JOINT

Non-steroidal anti-inflammatory drugs BNF section 10.1.1			
Ibuprofen 200mg tablets	(in section 10.1 of TAPG)	24	G
Ibuprofen 400mg tablets	(in section 10.1 of TAPG)	24	G
Ibuprofen SF suspension 100mg/5ml	(in section 10.1 of TAPG)	100ml	G
Rubefacients BNF section 10.3.2			
Transvasin®		40 g	b

Good practice points
Relative contra-indications to NSAIDs include heart failure, hypertension, renal impairment, peptic ulceration, caution in asthma; absolute contra-indications include proven hypersensitivity to aspirin or any NSAID.
The combination of a NSAID and low dose aspirin may increase the risk of gastro-intestinal side effects, this combination should be avoided if possible.

Examples of counselling points
NSAIDs must be taken with or after food.

When to refer
Suspected fracture.
Possible adverse drug reaction – falls, bruising.
Head injury.
Medication failure.
Arthritis.
Severe back pain.
Back pain (and/or pins and needles/numbness) radiating to the leg.

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INFECTIONS

VAGINAL CANDIASIS (THRUSH)

Topical imidazoles BNF section 7.2.2			
Clotrimazole 500mg vaginal pessary	(in section 7.2 of TAPG)	1	B
Clotrimazole 2% cream	(in section 7.2 of TAPG)	20 g	b
Clotrimazole 2% cream/500mg pessary combination		1	b
Oral imidazoles BNF section 5.2			
Fluconazole 150mg capsule	(in section 7.2 of TAPG)	1	G
** National PGD in place to allow supply of 1 capsule POM pack.**			
Fluconazole 150mg capsule/Clotrimazole 2% cream combination		1	b

Good practice points
Vaginal candidiasis should be treated with either an antifungal pessary or intravaginal cream inserted high into the vagina, or a single dose of oral fluconazole.
The application of topical antifungal creams are not always necessary but can be used to treat vulvitis and supplement primary treatment.
There is no evidence that treating the partner of a women suffering from candidiasis is helpful.
Fluconazole can be used in patients aged 16 to 60 years of age.

Examples of counselling points
Avoid strongly perfumed bath additives.
External creams need to be applied for seven days after symptoms have cleared.
Clotrimazole preparations have a damaging effect on latex condoms and diaphragms.

When to advise patient to contact their GP
Recurrent episodes of infection.
Signs of bacterial infection.
Unresponsive to appropriate treatment.
Diabetic patients.

FUNGAL SKIN INFECTIONS

Topical imidazoles BNF section 13.10.2			
Clotrimazole 1% cream	(in section 13.10 of TAPG)	20g	G
Terbinafine 1 % cream		7.5g	b
Terbinafine 1% spray		15ml	b
Topical imidazole with steroid BNF section 13.4			
Clotrimazole 1%/Hydrocortisone 1% cream	(in section 13.4 of TAPG)	15g	b

Good practice points
Refer to individual product details for conditions use licensed for.
Treatment with antifungal creams should be continued for 14 days after resolution of symptoms.
Patients should be advised of good foot hygiene and measures to prevent reinfection.
The licences for OTC terbinafine differ depending on preparation. All versions are licensed to treat tinea pedis (athlete's foot) and tinea cruris (Jock itch) and the spray and gel are licensed for tinea corpis (ringworm).
Terbinafine is not licensed for children 15 years and younger.
Combination of an imidazole and a mild corticosteroid is only indicated for treatment of athletes foot and fungal infections of skin folds with associated inflammation.

When to advise patient to contact their GP

B – prescribe and dispense (endorse) by brand G – reimbursed generic cost (part 7 DT), prescribe and dispense generically
b – one or more brand/manufacturer available can prescribe generically, but dispense (and endorse) by brand/manufacturer

Severe, affecting other parts of the foot.
Recurrent episodes of the infection.
Signs of bacterial infection.
Unresponsive to appropriate treatment.
Diabetic patients.
Involvement of toenails.

PREPARATIONS FOR WARTS AND VERRUCAE

Preparations for warts and calluses BNF section 13.7

Salatac®	(in section 13.7 of TAPG)	10g	b
Bazuka gel®		5g	b
Bazuka extra strength gel®		5g	b

Good practice points
The skin surface should be rubbed with a file or pumice stone, and the surrounding skin protected, before each application. If the application becomes painful, treatment should be withheld for a few days then recommenced.

Examples of counselling points
Apply carefully to affected area.
Protect surrounding skin with soft paraffin or plaster.
Rub surface of wart weekly with file or pumice.
Treatment may be required for up to 3 months.

When to advise patient to contact their GP
Changed appearance of lesions: colour, size.
Bleeding.
Itching.
Genital warts.
Facial warts.
Immuncompromised patients.

COLDSORES

Topical antiviral BNF section 13.10.3

Aciclovir 5% cream	(in section 13.10 of TAPG)	2 g	G

Good practice points
Aciclovir is best applied at the earliest possible stage, when prodromal changes of sensation are felt before vesicles appear.

Examples of counselling points
Wash hands regularly to avoid spreading the virus.
Use a separate towel for the cold sore area.

When to advise patient to contact their GP
Babies and young children.
Failure of an established sore to resolve (lasting longer than 2 weeks).
Severe or worsening sore.
History of frequent cold sores.
Painless sore.
Patients with atopic eczema.

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Eye affected.
Uncertain diagnosis.
Immunocompromised patients.

THREADWORM

Anthelmintics BNF section 5.5.1

Mebendazole 100mg tablet	(in section 16 Parasitic infections of TAPG)	1/person	b
Piperazine with sennosides oral powder		1 pack (2)/person	b

Good practice points
Personal hygiene before eating and after toileting should be emphasised.
If re-infection is suspected it is beneficial to give a second dose after 2 weeks. All family members should be treated at same time even if they have no symptoms.
Mebendazole is not licensed for children under two years; piperazine salts are less effective but licensed for this age group.

Examples of counselling points
Underwear should be worn in bed to prevent scratching.
Finger nails should be cut short.

When to advise patient to contact their GP
Infection other than threadworm suspected.
Recent travel abroad.
Medication failure
Pregnancy.

HEAD LICE

Silicone based products BNF section 13.10.4

Dimeticone 4% Lotion (Hedrin®)		50/150ml	B

Parasiticidal preparations BNF section 13.10.4

Malathion 0.5% Lotion (Prioderm®)	(in section 13.10 of TAPG)	50/200ml	b
Malathion 0.5% Liquid (Derbac-M®, Quellada M®)	(in section 13.10 of TAPG)	50/200ml	b

Head lice devices

Bug buster kit (kit contains 3 Bug Buster combs, 1 Nit Buster comb, 1 wide toothed comb and a protective cape)		See Drug Tariff

Good practice points
Dimeticone (Hedrin) has been shown in trials to have a similar efficacy to insecticide preparations, and head lice are unlikely to develop resistance to them. They can be applied as often as required. They may cause skin irritation for some individuals, however can be used in pregnant women, asthmatics and in young children from the age of 6 months. For these reasons it is reasonable to regard dimeticone as a first line treatment for head lice, particularly for those who do not wish to use insecticides. • Supply with NHS Tayside 'head louse infection' patient information leaflet, or 'guidance for the manual removal of head lice (wet combing)'. • Prescribe insecticides in quantities of 100ml per infected person, more if hair is longer and/or thick to allow two applications seven days apart. • Advise to check rest of family and to notify potential head to head contacts outwith the family to inspect their hair, e.g. close friends in neighbourhood and school or child minder/carer. This may include advising school/playgroup etc.

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Insecticides must not be used more than once a week for three consecutive weeks. They may cause skin irritation for some individuals. Alcoholic lotions are not recommended for small children or in individuals who have eczema or asthma.
For lice, only those with confirmed infection should be treated with insecticides. Treatment should be repeated after a 7 day period. If the infection is not eradicated after treatment once a week for three consecutive weeks, methods of application should be reviewed with the infected person or parent/carer. The alternative recommended insecticide, carbaryl can be prescribed by the GP.
Manual removal of head lice (the wet combing method) can be recommended as a method of treating head louse infection if the individual does not wish to use any chemical treatments. There continues to be little scientific evidence that manual removal of head lice is an effective way to treat head louse infection in a population. However the Scottish Executive recommends that wet combing should be offered to parents as an option.
The success of the wet combing method is totally reliant upon the commitment of the individual to carry it out and the systematic removal of live lice every three days over a period of three weeks.
Guidance on the wet combing method. The basic steps are: 1. Shampoo the hair and rinse as usual. 2. Blot hair lightly, leaving it wet. Use a small amount of conditioner if hair is thick or tangled. 3. Ensure good lighting to see clearly. 4. Use a fine toothed comb with teeth no more than 2mm apart. 5. Place a white piece of paper/card below the area to be combed, so head lice can be seen more easily if they fall. 6. Insert the comb at the roots of the hair and slowly run down the scalp for the full length of the hair. Look at the teeth of the comb and remove any lice and/or eggs onto a piece of disposable kitchen towel or toilet paper. 7. Continue this in small sections until the whole head has been combed and no lice have appeared on the comb. 8. Wash the comb with warm, soapy water, rinse and dry in between using again or on another person. Check that there are no lice or eggs adhering to the comb before it is used again. 9. Repeat all of the above in three day periods i.e. day 0,3,6,9 etc. taking three weeks to complete.
Detection combing should be advised in the usual way done weekly in conjunction with the insecticides to check for effectiveness.

SCABIES

Parasiticidal preparations BNF section 13.10.4

	Permethrin 5% (Lyclear Dermal Cream®)	(in section 13.10 of TAPG) 30g	b
	Malathion 0.5% Liquid (Derbac-M®, Quellada M®)	(in section 13.10 of TAPG) 50/200ml	b

Good practice points
Permethrin cream should be left on for eight to twelve hours before washing off. For cases, two applications seven days apart is recommended. Only one application is required for asymptomatic contacts. This product is not contraindicated in pregnancy or when breastfeeding.
Permethrin (Lyclear®) contains lanolin. For cases of lanolin allergy Malathion 0.5% aqueous liquid should be used and should be left on for 24 hours.
For scabies, lotions/creams should be applied to the whole body, taking care to treat the webs of fingers and toes, and brushing the preparation under the ends of finger nails. Supply with NHS Tayside 'information about scabies infection' patient information leaflet.
Treatments should be reapplied to any areas of the body, e.g. hands, which are washed during the application.

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b – one or more brand/manufacturer available can prescribe generically, but dispense (and endorse) by brand/manufacturer

URINARY TRACT DISORDERS

CYSTITIS

Drugs used for alkalinisation of urine BNF section 7.4.3

Potassium/sodium citrate sachets		6	b

Good practice points
Women with recurrent symptoms or symptoms suggestive of systemic disease should be referred to a GP, as should men or children presenting with symptoms of cystitis.
Patients with cystitis should increase their fluid intake.

Examples of counselling points
Avoid alcohol, tea and coffee as they can irritate the bladder.
Cranberry juice products have been shown to help prevent urinary tract infections.

When to advise patient to contact their GP
All men and children.
Associated fever, nausea/vomiting.
Loin pain or tenderness.
Haematuria.
Vaginal discharge.
Duration longer than 2 days.
Pregnancy.
Recurrent cystitis.
Failed medication.

EYE

ANTI-INFECTIVE EYE PREPARATIONS

Antibacterials BNF section 11.3.1

Chloramphenicol eye drops 0.5%*	(in section 11.3 of TAPG)	10 ml	G
** National PGD in place to allow supply of 10ml POM Pack. **			
Chloramphenicol 1% eye ointment	(in section 11.3 of TAPG)	4g	b

Good practice points
Most cases of acute bacterial conjunctivits are self-limiting. Treatment should be given if condition has not resolved spontaneously after 5 days.
If both eyes are infected two bottles should be dispensed, one for each each.
Contact lenses should not be worn until infection has resolved and for 24 hours after treatment is completed.
OTC chloramphenicol eye drops. http://www.rpsgb.org/pdfs/otcchloramphenicoleyedropsguid.pdf
Further information available in RPSGB practice guidance.

Good practice points
Patients with a suspected serious cause of 'red eye' should be referred to a GP immediately, e.g. moderate to severe eye pain, reduced and or blurred vision.

Examples of counselling points
Keep the product in the fridge.

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ANTI-INFLAMMATORY PREPARATIONS

Other anti-inflammatory preparations BNF section 11.4.2

Sodium cromoglicate 2% eye drops	(in section 11.4 of TAPG)	5/10 ml	B
Otrivine-Antistin® eye drops		10 ml	b

Also see Antihistamines and Nasal Allergy

Good practice points

Sodium cromoglicate is used to treat allergic conjunctivitis. It has a prophylactic action and must be used regularly even when symptoms improve. Patients should be advised that there may be several days before an effect and that instant relief should not be expected.

Otrivine-Antistin® can cause systemic effects and is not recommended for long term use.

Examples of counselling points

Once opened the eye drops should be discarded after 28 days.

TEAR DEFICIENCY/OCULAR LUBRICANTS

Tear deficiency, ocular lubricants BNF section 11.8.1

Hypromellose 0.3% eye drops	(in section 11.8 of TAPG)	10 ml	G
Lacri-Lube® eye ointment	(in section 11.8 of TAPG)	3.5/5 g	b
Carbomers (Geltears®/Viscotears®)	(in section 11.8 of TAPG)	10 g	b

Good practice points

The severity of the condition and patient preference will often guide the choice of preparation.

When to advise patient to contact their GP

If condition lasts longer than 2 weeks.

Pains or signs of infection, i.e. purulent discharge.

EAR

REMOVAL OF EAR WAX

Removal of ear wax BNF section 12.1.3

Olive oil	(in section 12.1 of TAPG)	92ml	G
Cerumol®		11 ml	b
Otex®		8 ml	b

Good practice points

Ear wax should only be removed only if it causes symptoms of discomfort or hearing loss.

Patients should be advised not to use cotton buds to clean ear wax as this can push the wax back towards the ear drum aggravating the impaction.

Some proprietary preparations containing organic solvents can irritate the meatal skin.

Examples of counsellling points

The patient should lie with the affected ear uppermost for 5-10 minutes after a generous amount of the softening remedy has been introduced.

NOSE

NASAL ALLERGY

Nasal steroid BNF section 12.1.1

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Beconase (beclometasone) allergy nasal spray (in section 12.2 of TAPG)		100 or 180	B

Good practice points
Patients should be advised that beclometasone nasal spray will take several days to take effect and instant relief should not be expected.

Topical nasal decongestants BNF section 12.2.2

Sodium chloride 0.9% nasal drops	(in section 12.2 of TAPG)	10 ml	b
Xylometazoline 0.1% drops	(in section 12.2 of TAPG)	10 ml	G
Xylometazoline 0.1% spray	(in section 12.2 of TAPG)	10ml	G
Xylometazoline 0.05% paediatric drops	(in section 12.2 of TAPG)	10 ml	G

Also see Systemic nasal decongestants

Good practice points
Sodium chloride 0.9% nasal drops may relieve nasal congestion by helping liquefy nasal secretions.
Topical nasal decongestants can lead to rebound congestion on withdrawal and should be used short-term (usually for no longer than 7 days).

MOUTH

ORAL ULCERATION AND INFLAMMATION

BNF section 12.3.1 and section 12.3.4

Adcortyl in Orabase® for mouth ulcers	(in section 12.3 of TAPG)	5 g	b
Difflam® 0.15% oral rinse	(in section 12.3 of TAPG)	200 ml	b
Difflam® 0.15% spray	(in section 12.3 of TAPG)	30 ml	b
Chlorhexidine 0.2% mouthwash	(in section 12.3 of TAPG)	300 ml	b
Calgel®		10g	b
Anbesol® oral liquid		6.5ml/15ml	b

Good practice points
There is some evidence that chlorhexidine gluconate may reduce the duration and severity of each episode of ulceration.
Benzydamine mouthwash can be used 10 minutes before meals to relieve pain in patients suffering form mouth ulcers.
If ulceration is very painful, recurrences are frequent and severe then the patients should be referred to their GP.

When to advise patient to contact their GP or dental practitioner
Duration of longer than 3 weeks.
Associated weight loss.
Involvement of mucus membranes.
Rash.
Suspected adverse drug reaction.
Diarrhoea.

ORAL THRUSH

Oropharyngeal anti-infective drugs BNF section 12.3.2

Daktarin® (miconazole) oral gel 24mg/ml	(in section 12.3 of TAPG)	15 g	b

Good practice points
Miconazole gel will be adsorbed from the oral mucosa and part of the dose will be swallowed. Potentiates activity of anticoagulants, antiepileptics and hypoglycaemic drugs.

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When to advise patient to contact their GP
Duration of longer than 3 weeks.
Associated weight loss.
Involvement of mucus membranes.
Rash.
Suspected adverse drug reaction.
Diarrhoea.

SKIN

ECZEMA AND ALLERGY

Soap substitutes BNF section 13.2.1

Aqueous cream	(in section 13.2 of TAPG)	100/500 g	G
Emulsifying ointment	(in section 13.2 of TAPG)	500 g	G

Emollients BNF section 13.2.1

Diprobase® cream or ointment	(in section 13.2 of TAPG)	50 g	b
Doublebase®	(in section 13.2 of TAPG)	100/500g	b
E45®	(in section 13.2 of TAPG)	50/125/500g	b
Epaderm®	(in section 13.2 of TAPG)	125/500g	B

Emollient bath additives BNF section 13.2.1.1

Oilatum® emollient	(in section 13.2 of TAPG)	250 ml	b

Good practice points
Emollients should be applied regularly to maintain improvement; most are best applied after a shower or bath.
Aqueous cream and emulsifying ointment are preferred as soap substitutes. Most emollients can be used as soap substitutes by wetting the skin first, then washing with cream or ointment, the rinsing off.

Examples of counselling points
Emollient bath additives make the bath slippy and patients should be warned of the risk of falling.
The practice of using an emollient immediately before a topical corticosteroid is inappropriate.

When to advise patient to contact their GP
Once only trial of emollient, if no improvement then refer to GP.

NAPPY RASH

Barrier preparations BNF section 13.2.2

Conotrane®	(in section 13.2 of TAPG)	100g	b
Sudocrem®	(in section 13.2 of TAPG)	125g	b
Metanium® ointment		30g	b

Good practice points
For nappy rash, advice should be given to parents/carers to ensure that nappies are changed frequently. The rash may clear when left exposed to the air.
When barrier preparations are used they should be applied liberally after each nappy change.

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BREASTFEEING MOTHERS (SORE/CRACKED NIPPLES/SUPERFICIAL BREAST CANDIDIASIS)

Emollients BNF section 13.2.1

Kamilosan® ointment		50g	B

Antifungal preparations BNF section 13.10.2

Miconazole 2% cream	(in section 13.10 of TAPG)	30g	b

Good practice points
Refer to PGD for miconazole cream in the treatment of superficial breast candidiasis for further information.

Examples of counselling points
Advice should be given on proper breastfeeding techniques and hygiene

When to advise patient to contact their GP
When inflammation is present.
When severe pain is present.

ALLERGY/ITCH

Topical local anaesthetics and antipruritic preparations BNF section 13.3

Calamine aqueous cream	(in section 13.3 of TAPG)	100ml	G
Calamine lotion	(in section 13.3 of TAPG)	200ml	G
Eurax® 10% cream	(in section 13.3 of TAPG)	30 g	b
Eurax® 10% lotion	(in section 13.3 of TAPG)	100 ml	b

Good practice points
Emollients are useful where pruritis is associated with dry skin.
Acute urticaria is usually self-limiting, and if mild, treatment is often unnecessary. Oral antihistamines are useful. Sedating oral antihistamines may be particularly helpful if sleep is disturbed.
Calamine lotion is useful for sunburn and chickenpox.

TOPICAL CORTICOSTEROIDS

BNF section 13.4

Hydrocortisone 1% cream	(in section 13.4 of TAPG)	15g	G
Hydrocortisone 1% ointment	(in section 13.4 of TAPG)	15g	G
Eumovate® 0.05% cream	(in section 13.4 of TAPG)	15g	b
Eurax HC® cream		15g	b

Good practice points
For use in irritant dermatitis, contact allergic dermatitis, insect bites reactions and mild to moderate eczema
Topical corticosteroids are not recommended in urticaria, rosacea, acne or undiagnosed, possibly infective disorders.
Topical corticosteroids should be applied thinly, only to the affected area for a maximum of 7 days. If the condition doses not improve, the patient should be referred to a GP.
A once daily application is often sufficient but topical corticosteroids should not be used more than twice a day.

ACNE

Topical preparations for acne BNF section 13.6.1

Panoxyl® 2.5, 5 and 10% aqueous gel (benzoyl peroxide) (in section 13.6 of TAPG)	40g	b

Good practice points
Severe/extensive cases of acne should be referred to the GP.
Benzoyl peroxide should be used in increasing strengths regularly to the entire acne prone area.

Examples of counselling points
Benzoyl peroxide may bleach clothing.

When to advise patient to contact their GP
Acne in the very young.
Severe acne.
Acne causing scarring.
Failed medication (no improvement in 2 months).
Suspected drug induced acne.

SCALP DISORDERS

Shampoos and other preparations for scalp and hair conditions BNF section 13.9

T/Gel® shampoo	(in section 13.5 of TAPG)	125 ml	b
Polytar® liquid		150/250ml	b
Ketoconazole shampoo	(in section 13.9 of TAPG)	60/100ml	B

Good practice points
Treatment depends on the severity of the condition. Shampoo formulations are preferred for moderate scaly scale conditions whereas more severe conditions may require an ointment.
Ketoconazole shampoo is often helpful for seborrhoeic dermatitis of the scalp.

CRADLE CAP

Detinox® cradle cap shampoo	125ml	b

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Patient Group Direction
For the Supply of Chloramphenicol Eye Drops 0.5% under the Minor Ailment Service

This Patient Group Direction (PGD) is a specific written instruction for the supply of Chloramphenicol Eye Drops 0.5% under the Minor Ailment Service to groups of patients who may not be individually identified before presentation for treatment.

This will enable a Community Pharmacist, registered as a member of the Royal Pharmaceutical Society, to supply/administer treatment under the Minor Ailment Service and in accordance with the following protocol and the recommendations of the Department of Health 1998, the NMC Code of Professional Conduct: Standards of Conduct, Performance and Ethics (2004) and the NMC Guidelines for the Administration of Medicines (2004).

The majority of clinical care should be provided on an individual, patient specific basis. The supply of medicines under Patient Group Directions should be reserved for those limited situations where this offers an advantage for patients care (without compromising patient safety) and where it is consistent with appropriate professional relationships and accountability.

Definition of clinical situation/condition	Conjunctivitis will give the sensation of a gritty or itchy eye or eyes, with possibly a purulent discharge or crusting of the eyelid margins. It will only have been present for a few days and is not associated with any reduction in vision. The affected eye(s) will often look slightly red/infected, but this is not usually very marked. Pain is not a feature of simple conjunctivitis.
Criteria for inclusion	Presentation in Community Pharmacy with a need for treatment of symptoms of bacterial conjunctivitis, and registered for the Minor Ailment Service (MAS).
Criteria for exclusion	Patient not participating in MAS. Children under 1 year. Pregnancy, Breast feeding. Known hypersensitivity to chloramphenicol, benzalkonium chloride or disodium edetate.
Action if excluded	Refer to GP.

Characteristics of staff authorised to take responsibility for the supply or administration of medicines under this patient group direction

Qualifications Required	Community pharmacist registered as a member of the Royal Pharmaceutical Society
Additional Requirements	
Continuing Training Requirements	

DESCRIPTION OF TREATMENT AVAILABLE UNDER THIS PATIENT GROUP DIRECTION

Name of Medicine	Chloramphenicol eye drops 0.5%
POM/P/GSL	POM
PGD Ref No	
Dose/s	Adults and children 1 years and over – Apply one (1) drop at least every two (2) hours then reduce frequency as infection is controlled and continue for 48 hours after healing.
Route	Ocular
Total dosage	For a total of five (5) days
Total treatment quantity	10ml
Advice to be given to the patient	Patient Information Leaflets. Contact lenses should be removed during period of treatment. Continue for at least 48 hours after the eye appears normal, up to a maximum of 5 days treatment. Store in a fridge (between 2-8º), and keep cap tightly closed between applications. Discard 28 days after opening.
Identification and management of possible adverse effects	Occasional: Transient stinging on instillation. Rare: Allergic reaction (persistent burning, swelling of lids)
Referral for medical advice	Urgent referral: – if painful, rather than itchy or gritty – if reduced visual acuity – if eye looks cloudy – if pus level visible in anterior chamber – if any history of trauma to eye, or grinding, immediately prior to onset of symptoms – if possibility of foreign body on/in eye – if history of welding without eye protection immediately prior to onset of symptoms – if no improvement within 48 hours Routine referral: – pregnancy – breast feeding
Facilities and supplies required	
Treatment Records	Following to be noted in the computerised patient information records and on the CP 2 form: • Dose, frequency and the quantity supplied • Date of supply to patient
Patients on concurrent medication	Patients should be advised to allow at least 5 minutes between administration of two different eye drop preparations.

Patient Consent	Prior to the supply of chloramphenicol eye drops 0.5%, consent must be obtained from the patient,parent or guardian. There is no legal requirement for consent to be in writing but written consent does serve to provide a permanent record that the individual (patient parent or guardian) has been informed about the process, benefits and risks of chloramphenicol eye drops 0.5%. Individuals (patient, parent or guardian) should also be informed about how data will be stored, who will be able to access that information and how the data may be used If a patients fitness and suitability cannot be established, supply should be deferred and the patient referred to their doctor. Written and verbal information should be available in a form that can be easily understood by the person who will be giving the consent. Where English is not easily understood, translations and properly recognised interpreters should be used. **Consent to supply to children** • A patient under 16 years of age may give consent ,provided he or she understands fully the benefits and risks involved. The patient should be encouraged to involve a parent/guardian, if possible in the decision. • For young children not competent to give or withhold consent, such consent can be given by a person with parental responsibility.
Audit Trail	

Adverse Reactions	In the event of a Suspected Adverse Drug Reaction, please complete a yellow card and submit to the Committee on Safety of Medicines. A supply of these forms can be found at the rear of the British National Formulary. Record findings, advice and actions in person's record.

NHS Tayside

MANAGEMENT & MONITORING OF PATIENT GROUP DIRECTION

Adopted from National PGDs:

Medical Practitioner: Dr Andrew Russell Signature:

Pharmacist: Mr John Hamley Signature:

Tayside Area Drug & Therapeutics Committee:

Name: Professor Dilip Nathwani Signature:

Approved By:

Name: Professor Stewart Forsyth
Medical Director, Single Delivery Unit Signature

Date Effective: 1 July 2006

Review Date: 1 July 2008

Plans must be made to ensure completion of a review on or by the date above. The revised PGD will then follow on immediately. If the review date is reached and no review has taken place, then the PGD will be null and void. Interim review will be required as and when new safety information comes to light.

Declaration

This protocol is authorised for use with _____
(practice/hospital etc) by the individuals named below

Doctor…… Date……

I have read and fully understand this PGD and agree to provide this medicine only in accordance with this PGD.

Name of Pharmacist ……..…….……...

RPSGB Registration Number…….

Normal Pharmacy Location……..……

Signature …….

Date ……..…….

Note:

A copy of this agreement must be signed by each pharmacy practitioner who wished to be authorised to use the PGD for the supply of Chloramphenicol Eye Drops under MAS.

Each authorised pharmacy practitioner should be provided with an individual copy of the clinical content of the PGD and a photocopy of the document showing their authorisation.

REGISTER OF NAMED INDIVIDUALS WHO MAY SUPPLY CARE UNDER THIS PATIENT GROUP DIRECTION

Date	Name	Qualifications

PATIENT GROUP DIRECTION TREATMENT RECORD SHEET

A treatment record sheet is required for each patient treated under a Patient Group Direction

PATIENT GROUP DIRECTION PATIENT INFORMATION SHEET

A patient information sheet has to be given to each patient treated under a Patient Group Direction

Patient Group Direction
For the Supply of Fluconazole 150mg under the Minor Ailment Service

This Patient Group Direction (PGD) is a specific written instruction for the supply of Fluconazole 150mg capsule under the Minor Ailment Service to groups of patients who may not be individually identified before presentation for treatment.

This will enable a Community Pharmacist, registered as a member of the Royal Pharmaceutical Society, to supply/administer treatment under the Minor Ailment Service and in accordance with the following protocol and the recommendations of the Department of Health 1998, the NMC Code of Professional Conduct: Standards of Conduct, Performance and Ethics (2004) and the NMC Guidelines for the Administration of Medicines (2004).

The majority of clinical care should be provided on an individual, patient specific basis. The supply of medicines under Patient Group Directions should be reserved for those limited situations where this offers an advantage for patients care (without compromising patient safety) and where it is consistent with appropriate professional relationships and accountability.

Definition of clinical situation/condition	Candidiasis is a yeast infection caused by the Candida species of fungus, usually Candida albicans. Many women are affected by vaginal thrush at some point in their lives and in some women it may recur regularly. The condition develops when Candida albicans, which is often present in the vagina, causes itching, irritation, discharge, redness, soreness and swelling of the vagina and vulva and a thick, white vaginal discharge.
Criteria for inclusion	Women with previous history of vaginal candidiasis presenting in Community Pharmacy with a need for treatment of symptoms of vaginal candidiasis, and registered for the Minor Ailment Service (MAS).

Criteria for exclusion	• Under 16 and over 60 years of age • Women who are experiencing the symptoms for the first time • Liver and kidney disease • Risk of sexually transmitted disease (STD) or other cause for vaginal discharge • Irregular or abnormal vaginal pain, bleeding or blistering • Genital ulceration • Known hypersensitivity to fluconazole • More than two infections of thrush within the last six months or second request within 1 month • Pregnancy • Breast feeding • A known diabetic with recurrent candidiasis
Action if excluded	Refer to GP.

Characteristics of staff authorised to take responsibility for the supply or administration of medicines under this patient group direction

Qualifications Required	Community pharmacist registered as a member of the Royal Pharmaceutical Society
Additional Requirements	
Continuing Training Requirements	

DESCRIPTION OF TREATMENT AVAILABLE UNDER THIS PATIENT GROUP DIRECTION

Name of Medicine	Fluconazole 150mg capsule
POM/P/GSL	POM
PGD Ref No	
Dose/s	Vaginal candidiasis – a single dose of 150mg by mouth
Route	Oral
Total dosage	150mg
Total treatment quantity	One capsule completes the course
Advice to be given to the patient	• Provide Patient Information Leaflet. • Treat at any time of menstrual cycle, including during periods. • Discuss any possible side effects with the patient. • Advise regarding re-infection and that partner may need treatment if symptomatic. • Washing the vaginal area with water only, avoiding the use of perfumed soaps, vaginal deodorants or douches. • Avoiding using latex condoms, spermicidal creams and lubricants if they cause irritation. • Wearing cotton underwear and loose-fitting clothes if possible.
Identification and management of possible adverse effects	Occasional: nausea, abdominal discomfort, diarrhoea, flatulence, headache, rash. Rare: dyspepsia, vomiting, taste disturbance, hepatic disorders, hypersensitivity reactions, anaphylaxis, dizziness, seizures, alopecia, pruritus, toxic epidermal necrolysis, Stevens-Johnston syndrome, hyperlipidaemia, leocpenia, thrombocytopenia, hypokalaemia. Also see BNF.
Referral for medical advice	Urgent referral: Not applicable. Routine referral: • If symptoms not clearing within 3 days • Pregnant • Breast feeding • Hepatic or Renal impairment • Known diabetic and recurring candisiasis • Second request within one month • Vaginal pain, bleeding or blistering
Facilities and supplies required	

Treatment Records	Following to be noted in the computerised patient information records and on the CP 2 form: • Dose, frequency and the quantity supplied • Date of supply to patient
Patients on concurrent medication	
Patient Consent	Prior to the supply of fluconazole, consent must be obtained from the patient. There is no legal requirement for consent to be in writing but written consent does serve to provide a permanent record that the individual (patient parent or guardian) has been informed about the process, benefits and risks of fluconazole. Individuals (patient, parent or guardian) should also be informed about how data will be stored, who will be able to access that information and how the data may be used If a patients fitness and suitability cannot be established, supply should be deferred and the patient referred to their doctor. Written and verbal information should be available in a form that can be easily understood by the person who will be giving the consent. Where English is not easily understood, translations and properly recognised interpreters should be used.
Audit Trail	
Adverse Reactions	In the event of a Suspected Adverse Drug Reaction, please complete a yellow card and submit to the Committee on Safety of Medicines. A supply of these forms can be found at the rear of the British National Formulary. Record findings, advice and actions in person's record.

NHS Tayside

MANAGEMENT & MONITORING OF PATIENT GROUP DIRECTION

Adopted from National PGDs:

Medical Practitioner: Dr Andrew Russell Signature:

Pharmacist: Mr John Hamley Signature:

Tayside Area Drug & Therapeutics Committee:

Name: Professor Dilip Nathwani Signature:

Approved By:

Name: Professor Stewart Forsyth
Medical Director, Single Delivery Unit Signature

Date Effective: 1 July 2006

Review Date: 1 July 2008

Plans must be made to ensure completion of a review on or by the date above. The revised PGD will then follow on immediately. If the review date is reached and no review has taken place, then the PGD will be null and void. Interim review will be required as and when new safety information comes to light.

Declaration

This protocol is authorised for use with _____
(practice/hospital etc) by the individuals named below

Doctor…… Date ……

I have read and fully understand this PGD and agree to provide this medicine only in accordance with this PGD.

Name of Pharmacist ……..…….……...

RPSGB Registration Number…….

Normal Pharmacy Location……..……

Signature …….

Date ……..…….

Note:

A copy of this agreement must be signed by each pharmacy practitioner who wished to be authorised to use the PGD for the supply of Fluconazole 150mg capsules under MAS.

Each authorised pharmacy practitioner should be provided with an individual copy of the clinical content of the PGD and a photocopy of the document showing their authorisation.

REGISTER OF NAMED INDIVIDUALS WHO MAY SUPPLY CARE UNDER THIS PATIENT GROUP DIRECTION

Date	Name	Qualifications

PATIENT GROUP DIRECTION TREATMENT RECORD SHEET

A treatment record sheet is required for each patient treated under a Patient Group Direction

PATIENT GROUP DIRECTION PATIENT INFORMATION SHEET

A patient information sheet has to be given to each patient treated under a Patient Group Direction

Patient Group Direction
For The Supply of Miconazole Cream

This Patient Group Direction (PGD) is a specific written instruction for the supply of Miconazole to groups of breast-feeding women who may not be individually identified before presentation for treatment. This PGD is for use within NHS Tayside.

This PGD will enable any designated registered health professional to supply/administer treatment in accordance with the following protocol and the recommendations of the Department of Health 1998, and with cogniscence to their relevant professional guidance such as the NMC Code of Professional Conduct: Standards of Conduct, Performance and Ethics (2004) and the NMC Guidelines for the Administration of Medicines (2004) and the NHS Tayside Policy on the Safe and Secure Handling of Medicines.

The majority of clinical care should be provided on an individual, patient specific basis. The supply of medicines under Patient Group Directions should be reserved for those limited situations where this offers an advantage for patient care (without compromising patient safety) and where it is consistent with appropriate professional relationships and accountability.

Definition of Clinical Situation / Condition	The patient presents with superficial breast candidiasis
Criteria For Confirmation Of The Clinical Condition	The woman describes a stabbing, shooting pain which increases after a breast feed has finished; increased nipple sensitivity. Nipples may be red and flaky or blanched. History of recent antibiotic therapy may be present. Baby may have oral candidiasis.
Criteria For Inclusion	The patient may receive care under this PGD if she presents with symptoms suggestive of superficial breast candidiasis
Criteria For Exclusion	The patient must be excluded from receiving treatment under this PGD if one or more of the following applies: • the patient requests to consult with a medical practitioner on this occasion; • the patient has uncertainty about the safety of miconazole despite counselling; • the patient has not given informed consent; • there is hypersensitivity to the active substance or any of the excipients;
Action To Be Taken If The Patient Declines Or Does Not Adhere To Or Is Excluded From Receiving Treatment Under This PGD	Miconazole must not be supplied. The consultation must be documented on the PGD patient record proforma. The practitioner must refer the patient to a medical practitioner as soon as possible.
Caution Must Be Exercised In The Following Circumstances:	The patient takes a medicine known to interact with miconazole. A list of interacting medicines can be found in standard information sources such as the British National Formulary (BNF Appendix 1).
Action To Be Taken If The Patient is Identified As Having One Or More Of The Criteria For Caution	Miconazole can be supplied on prescription after consultation with a medical practitioner

Characteristics Of Staff Authorised To Take Responsibility For The Supply Or Administration Of Medicines Under This Patient Group Direction

Qualifications Required	A registered practitioner enabled to administer or supply medicines under HDL (2001) 7
Additional Training Requirements	Successful completion of Tayside training programme for supply of miconazole cream under PGD
Continuing Training Requirements	Professional accountability and personal responsibility to maintain competence

Description Of Treatment Available Under This Patient Group Direction

Name of Medicine	Miconazole Cream 2% 30g
POM/P/GSL	Pharmacy
Dose/s	For cutaneous use. Apply the cream sparingly twice daily to the affected areas. Treatment should be prolonged for 10 days after the problem has disappeared to prevent relapse.
Route	Topical
Total Dose Number	One 30g tube
Advice To Be Given To The Patient	Offer a follow up appointment if the patient has any concerns and explain the arrangements for seeking advice if the patient experiences any other problems or concerns about treatment. Verbal Advice Ensure the patient understands verbal instruction, then discuss: • To avoid reinfection, both the mother and baby should be treated simultaneously. The baby will require a suitable product for treatment of oral candida. • the mode of action, efficacy and failure rate of the treatment; the method and manner of administration of the treatment; • Advise about skin irritation that disappears on discontinuation of therapy; • Advice on use of paracetamol to manage discomfort until symptoms improve; • Advise on follow up. Written Advice Issue or ensure the patient has a copy of: • the manufacturer's Patient Information Leaflet;
Identification and management of possible adverse effects	• The patient must be advised to contact the place of issue or other appropriate practitioner if she is concerned about any changes in her health that she feels may be due to miconazole. • The patient must be advised to contact the place of issue or other appropriate practitioner if she is concerned about any circumstance that may affect the efficacy of miconazole. • The patient must be asked to report any adverse outcomes / side-effects to the place of issue as soon as possible. If the patient contacts the place of issue with any of the above scenarios she should be referred to a suitable practitioner for management of the adverse effect

Supplies And Resources Available At Sites Where Care Under This PGD Is Provided	Supplies: The patient will be issued with one tube of 30g Miconazole 2% cream obtained from a pharmacy and which: • is within the manufacturer's expiry date; • appropriately labelled Resources The following will be available to for reference (current editions): • Summary of Product Characteristics for Miconazole • British National Formulary; • www.nes.scot.nhs.uk/pharmacy/breastfeeding
Treatment Records and Audit Trail	• The patient record proforma will be completed for each consultation made under this PGD. This will be completed when the patient is present. • Verbal consent must be recorded on this proforma if written consent is unavailable. • Record in patient medication record that a PGD has been completed and sign and date this entry, if appropriate. • Record type of medication and amount supplied on form. • A record of each consultation will also be made in a register, reserved solely for recording PGD consultations. This will detail: the date of the consultation, the patient identification (name, date of birth and community health index,), the reference number of the PGD used, the batch number and expiry date of the product used and the consulting practitioner's name and signature. The above records will be audited yearly and must be retained for six years. If the patient is under 18 on first presentation, the records must be kept until she / he is 25 years old.
Patients on concurrent medication	A medication history for each patient should be taken in order to identify potential concurrent medicines that may affect the treatment offered through this PGD.
Patient Consent	The patient will be given the defined information and written consent sought. The consent is documented on a copy of the patient treatment form attached to this PGD or in the patient's notes.
Adverse Reactions	All adverse reactions (actual and suspected) will be recorded on the patient record. The patient should be advised to contact their General Practitioner if further advice about management of the adverse reaction is required. Where appropriate a Yellow Card Report will be forwarded to the Committee on Safety of Medicines. A supply of these forms can be found at the rear of the British National Formulary.

Management and monitoring of Patient Group Direction

Developed By:

Lead Practitioner: Signature:_____ Janet Dalzell

Medical Practitioner: Signature:_____ Morag Martindale

Nurse: Signature:_____ Janet Dalzell

Pharmacist: Signature:_____ Andrew Radley

Approved By:

Lead Clinician Fiona Greig

Name:
Signature _____

Tayside Area Drug & Therapeutics Committee

Name: Professor Dilip Nathwani Signature:

Date Effective: 1 February 2008

Review Date: 1 February 2010

Plans must be made to ensure completion of a review on or by the date above. The revised PGD will then follow on immediately. If the review date is reached and no review has taken place, then the PGD will be withdrawn from use. Interim review will be required as and when new safety information comes to light.

Declaration for Local Implementation

This protocol is authorised for use within _____
(practice/hospital etc) by the individuals named below

Signed……..……Clinical Practice Manager Date ……

I have read and understood this PGD and have received the specified training to implement it effectively.

Signed ……. Date …….

Name …….. Designation ……

Signed ……. Date …….

Name …….. Designation..……..

Signed ……. Date …….

Name …….. Designation ……...

Signed ……. Date …….

Register of named individuals who may supply care under this Patient Group Direction

Date	Name	Qualifications

Patient Group Direction Patient Record
Proforma For The Supply Of Miconazole 2% Cream Under Patient Group Direction

1. PATIENT AND CONSULTATION DETAILS	
Date of Consultation	
Patient Name	
CHI	
Place of Issue	

2. PATIENT HISTORY AND EXAMINATION	
Does the patient present with symptoms of superficial breast candidiasis	Details

3. CRITERIA FOR INCLUSION

The patient may receive care under this Patient Group Direction (PGD) if she/he presents with symptoms of superficial breast candidiasis

4. CRITERIA FOR ABSOLUTE EXCLUSION

The patient must be excluded from receiving treatment under this PGD, and referred to a medical practitioner as soon as possible, if one or more of the following criteria apply:

The patient takes anticoagulant therapy or sulphonylurea hypoglcaemics (phenytoin)	□ Yes	□ No
The patient requests to consult with a medical practitioner on this occasion	□ Yes	□ No
The patient has uncertainty about the safety of miconazole despite counselling	□ Yes	□ No
In so far as it can be ascertained the patient has not given informed consent	□ Yes	□ No
The patient is hypersensitive to the active substance or any of the excipients	□ Yes	□ No
the patient requests to consult with a medical practitioner on this occasion;	□ Yes	□ No
5. CRITERIA FOR CAUTION If the patient is taking a medicine known to interact with miconazole ,		

6. COUNSELLING		
Mode of action, efficacy and failure rate discussed?	□ Yes	□ No
Method and manner of administration discussed?	□ Yes	□ No
Advise about skin irritation that disappears on discontinuation of therapy;	□ Yes	□ No
Advise on use of paracetamol to manage discomfort until symptoms improve;	□ Yes	□ No
Advise on follow up	□ Yes	□ No
Issue written information	□ Yes	□ No

7. ACTION TAKEN

Supply

Miconazole 2% Cream to applied sparingly twice daily to the affected area and for up to 10 days after symptoms have disappeared to prevent relapse	□ Yes	□ No
Batch number of Miconazole 2% cream supplied		
Expiry date of Miconazole 2% cream supplied		

Referral

Referred to:	
Advice Given:	

8. DECLARATION

The above information is correct to the best of my knowledge. I have been counselled on the use Miconazole and understand the advice given to me by the practitioner.

Patient's Signature: Date:

The patient is unable to give written consent. She has given verbal consent.

Practitioner's Signature: Date:

The action specified was based on the information given to me by the patient, which, to the best of my knowledge, is correct

Practitioner's Signature: Date:

Patient Group Direction Patient Information Sheet

A patient information sheet has to be given to each patient treated under a Patient Group Direction

The treatment you have received today is an antifungal cream called Miconazole.

This antifungal cream is used to treat breast Candida. Candida is a fungal infection, which can cause pain, redness, and sensitivity of the nipple. Miconazole if taken as instructed will effectively clear this infection.

Apply the cream sparingly twice daily to the affected areas. Treatment should be prolonged for 10 days after the problem has disappeared to prevent relapse.

Treatment of the baby's mouth with an appropriate product should be undertaken at the same time as this course of treatment.

You may need to take a pain killer such as paracetamol until symptoms improve.

If at any time you are unsure please call and ask to speak to your Health Advisor or pharmacist.