

**Prescribing for Clinical Need
&
Gluten Free foods Policy**

DRAFT

Version Control

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Patient and Public Engagement

The principles of the policy were discussed by Heywood Middleton and Rochdale Clinical Commissioning Committee who agreed that NHS spending should be evidence based and cost effective. The CCG will undertake an engagement process on the proposed policies with key stakeholders in Q4 2015/16

1. Summary

The Clinical Commissioning Committee of HMR CCG advises that only treatments that are clinically effective and provide a clear health benefit to patients should be prescribed on NHS prescriptions. All other treatments should be considered a low priority and are detailed within this policy.

Criteria for inclusion on the Low Priority Prescribing List:

1. Treatments for minor ailments.
2. Treatments where there is insufficient evidence of clinical benefit or cost-effectiveness.
3. Preparations where there may not be a clinical need to treat.

Clinicians should only prescribe medicines that are known to be clinically effective and provide a health benefit to the patient.

2. Policy Rationale

Heywood Middleton and Rochdale CCG is keen to ensure that only treatments that are clinically effective and provide a clear health benefit to patients are prescribed on NHS prescriptions. This is to ensure that CCG resources provide interventions with a proven health gain for the population. Therefore HMR CCG recommends that clinicians prioritise resources based on evidence of the clinical effectiveness and safety of treatments, their cost effectiveness, and on which interventions provide the best health outcomes.

In the case of treatments which can be prescribed on NHS prescriptions, the CCG is reviewing treatments that provide limited health benefit. They should be considered a LOW PRIORITY and not suitable for prescribing unless patients fall into an exception category.

Some medicines that are used to treat minor ailments do not require the patient to be seen by a GP or Nurse employed within General Practice. These products can be purchased from pharmacies and supermarkets. Pharmacists and other trained staff members are expert on providing advice around minor ailments; they are easy to access without an appointment and most local pharmacies provide HMR CCGs local Minor Ailments Scheme (MAS). Use of the MAS will free up GP time to see more complex patients.

Some other products are clinically ineffective or are not cost effective. These treatments will not have undergone rigorous clinical trials to demonstrate that they are effective. It is inappropriate to direct NHS resources towards products that do not have proven efficacy or safety in preference to licensed medicines. HMR CCG encourages clinicians to refer to the formulary chapters, Do Not Prescribe and other recommendations produced by the Greater Manchester Medicines Management Group (GMMMGM)

3. Treatments for minor ailments

Many minor ailments are generally not of a serious nature and can be often managed by the individual. Products aimed at treating the symptoms of many of these ailments may not offer value for money and should not normally be prescribed at NHS expense

Other minor ailments are treated with products available without prescription. These products can be bought from a local Community Pharmacy or supermarket, and all these conditions can be treated through a locally run minor ailment scheme available at most local Community Pharmacies, if required.

See Appendix 1 for examples of these minor ailments.

4. Treatments where there is insufficient evidence of clinical benefit or cost-effectiveness

Many of the products in this category (listed in Appendix 2) are not licensed drugs under the Medicines Act. This means that they have not undergone the stringent testing laid down by the regulatory authorities to confirm their safety, quality and efficacy. There is no summary of product characteristics (SPC) for prescribers to consult and hence no indemnity for prescribers should the treatment cause harm.

Many of these products are classed as 'food substitutes' and are not covered by ACBS¹ regulations and/or do not appear in the current British National Formulary (BNF) or the Drug Tariff. They are often not manufactured to the same high pharmaceutical standards used for licensed medicines; hence there is no guarantee of consistency in formulation and potency. These treatments will not have undergone rigorous clinical trials to demonstrate that they are effective. It is inappropriate to direct NHS resources towards products that do not have proven efficacy or safety in preference to licensed medicines.

5. Preparations where there may not be a clinical need to treat

Within this category there are treatments that are clinically and cost effective when used in some patients, but not when used more widely. Also, some treatments are clinically effective but are not considered to be a good use of NHS resources. If prescribing is deemed to be clinically necessary, only those products listed in the Greater Manchester Medicines Management Group (GMMM²) Formulary² should be prescribed.

Clinicians will be required to consider whether the benefit of prescribing a treatment for an individual justifies the expense to the NHS. **Such judgements should be based purely on clinical factors and should not be influenced by socio-economic aspects such as the patient's ability to purchase.**

6. Prescribing Gluten Free Foods

The costs for these products are now considerably less than when the need for gluten free foods for patients with any diagnosed gluten sensitive enteropathy was identified. These foods are now widely available in local supermarkets and other food outlets at prices which are comparable to conventional (gluten containing) equivalents. In order to prioritise scarce NHS

¹ Advisory Committee on Borderline Substances

² http://gmmmg.nhs.uk/html/formulary_bnf_chapters.html

resources and ensure equitable treatments are available to all, HMR CCG proposes that the prescribing of Gluten Free (GF) Foods is restricted only to children aged less than 16 years of age, pregnant and breastfeeding women. All other patient groups will be required to purchase GF foods from local outlets.

Appendix 1: List of Minor Ailments & Available Treatments

Minor ailment condition	Treatment	Other brands to be aware of (N.B. this is not an exhaustive list)	Exceptions
Acute pain, headache, temperature	Paracetamol 500mg tablets* Paracetamol 500mg caplets Paracetamol 500mg capsules Paracetamol 500mg soluble tablets	Anadin Mandalol Diprol Panadol Hedex Panadol Advance.	Long term conditions requiring regular pain relief.
	Ibuprofen 200mg tablets Ibuprofen 200mg caplets Ibuprofen 200mg liquid capsules Ibuprofen 400mg tablets* Ibuprofen 100mg/5ml Susp*	Anadin Ibuprofen Mandafen Anadin Joint Pain Manorfen Anadin liquifast Nurofen Calprofen Orbifen Cuprofen Phor Pain Hedex	
	Co-codamol 8/500 mg tablets* Co-codamol 8/500mg capsules Co-codamol 8/500mg dispersible tablets Co-codamol 8/500mg effervescent tablets	Migraleve Yellow tabs Paracodol caps Paracodol soluble tabs	
	Paracetamol 120mg/5ml oral susp (sugar free)* Paracetamol 250mg/5ml oral susp (sugar free)*	Calpol Six Plus susp 250mg/5ml Calpol Infant susp 120mg/5ml Mandalol Medinol Sootheze Six Plus	Children under 2 months. Analgesia provided immediately post vaccination Babies born before 37 weeks. Babies weighing less than 4kg.
Athletes foot	Miconazole cream 2%*	Daktarin	Diabetic patients.
	Lamisil Once Cutaneous Solution 1%*	Lamisil AT (cream, gel, spray) Scholl advanced (cream, powder & spray)	Diabetic patients. Pregnancy. Breast feeding.
Bites/stings	Hydrocortisone cream 1%*	HC45 cream Lanacort cream	Children under 10 years. Pregnancy. Eyes or face, ano-genital area or on broken or infected skin. Long term skin conditions requiring regular treatment.
	Chlorphenamine 4mg tabs*	Allercalm Piriton tabs 4mg Hayleve Pollenase tabs Piriton Allergy tabs 4mg	Children under 12 years. Pregnancy. Breast feeding.
	Chlorphenamine oral solution 2mg/5ml(sugar free)* Chlorphenamine solution 2mg/5ml*	Allerief oral soln Piriton 2mg/5ml syrup	Children under 1 yr. Children with asthma. Children taking monoamine oxidase inhibitors.
	Loratidine 10mg tabs*	Clarityn Allergy tabs Clarityn Rapide tabs	Children under 2 yrs. Children 2-12 years weighing less than 30kg. Pregnancy. Breast feeding.

Cold sores	Aciclovir cream 2%*	Cymex Ultra Virasorb Lypsyl Vectavir	Zovirax	Immunocompromised & terminally ill. Children under 12 years.
Minor ailment condition	Treatment	Other brands to be aware of (N.B. this is not an exhaustive list)		Exceptions
Conjunctivitis (uncomplicated)	Chloramphenicol 0.5% eye drops* Chloramphenicol 1% eye ointment*	Brochlor Golden Eye Optrex Infected Eye Ointment Lumicare Eye Ointment Tubilux Eye Drops		Children under 2 years. Pregnancy
Diarrhoea	Dioralyte sachets* Electrolade sachets*	Dioralyte Relief		None
	Lopermide caps 2mg*	Diah-limit Imodium Diaquette Norimode Diocalm Ultra Normaloe Entrocalm		Children under 12 years. Inflammatory bowel disease. Post bowel surgery. Post pelvic radiation. Colorectal cancer.
Ear Wax	Olive Oil*	Almond Oil EarCalm Otex Exterol Cerumol Waxsol Sodium Bicarbonate Molcer		None
Hay fever	Acrivastine 8mg caps	Benadryl Allergy Relief caps 8mg Benadryl Plus Caps		Children under 12 years.
	Beclomethasone nasal spray*	Beconase hayfever spray Nasobec aqueous spray Pollenase nasal spray Vivabec Spray		Children under 6 years.
	Cetirizine 10mg tabs*	Benadryl tabs Piriteze Histease Zirtek tabs Pollenshield Hayfever		Children under 12 years. Patients with kidney problems. Pregnancy. Breast feeding.
	Cetirizine 1mg/ml oral solution	Benadryl Allergy Relief soln 1mg/1ml S/F Zirek Allergy soln 1mg/ml		
	Chlorphenamine 4mg tabs*	Allercalm Piriton tabs 4mg Hayleve Pollenase tabs Piriton Allergy tabs 4mg		Children under 12 years. Pregnancy. Breast feeding.
	Chlorphenamine oral solution 2mg/5ml(sugar free)* Chlorphenamine solution 2mg/5ml*	Allerief Oral soln Piriton 2mg/5ml syrup		Children under 1 year. Children with Asthma. Children taking monoamine oxidase inhibitors.
	Loratidine 10mg tabs *	Clarityn Rapide tabs Clarityn Allergy tabs		.Pregnancy. Breast feeding.
	Loratidine 5mg/5ml syrup*	Clarityn Allergy Syrup		Children under 2 years Children 2-12 years weighing less than 30kg. . Pregnancy.

			Breast feeding.
	Sodium Cromoglycate 2% Eye Drops*	Allercrom Optrex Allergy Catacrom Allergy Relief Pollenase Cromolux Hayfever Opticrom Hayfever	None
Minor ailment condition	Treatment	Other brands to be aware of (N.B. this is not an exhaustive list)	Exceptions
Head lice	Malathion Aqueous Lotion 0.5%*	Derbac-M Liquid 0.5%*	Babies under 6 months.
	Dimethicone Lotion 4% *	Hedrin* Linicin Lyclear Mousse Lyclear Repellant Nitrid Spray Nyda Spray	Babies under 6 months.
Indigestion, heartburn, Upset Stomach	Gaviscon Advance tabs* Gaviscon Advance liquid*	Gaviscon 250 tabs Gaviscon Cool (tabs & liquid) Gaviscon Double Action (tabs & liquid)	Children under 16 years
	Omeprazole 10mg*	Zanprol tabs	Children under 16 years. Patients prescribed Nelfinavir (HIV)
Infant colic	Infacol Suspension 40mg/ml S/F*,	Dentinox Infant colic drops	None
Nappy rash	Metanium* Sudocrem*	Bepanthen Drapolene Morhulin Zinc & Castor Oil	None
Nasal congestion	Sodium Chloride 0.9% Nasal Drops* Sodium Chloride 0.9% Nasal Spray	Snufflebabe nasal drops Calpol Soothe & Care (nasal drops & spray) Mandanol nasal drops,	None
Scabies	Permethrin 5% dermal cream*	Lyclear Lythrin	Babies under 2 months.
	Crotamiton 10% cream*	Eurax	Pregnancy.
	Chlorphenamine 4mg tabs* Chlorphenamine oral solution 2mg/5ml(sugar free)*	Allercalm Hayleve Piriton Allergy tabs 4mg Piriton tabs 4mg Pollenase tabs	Children under 1 year. Breast feeding.
Teething	Bonjela Teething Gel*	Anbesol teething gel Calgel teething gel Dentinox (teething gel & toothpaste)	Babies under 2 months. Heart disease. Liver disease.
	Paracetamol 120mg/5ml oral susp(sugar free)*	Calpol Infant susp 120mg/5ml Mandanol Infant Medinol	Babies under 2 months. Babies born before 37 weeks. Babies weighing less than 4kg.
Threadworms	Mebendazole 100mg tabs* Pripsen Sachets*	Ovex	Under 2 years. Pregnancy. Breast feeding.
Vaginal thrush	Clotrimazole cream 1%* Clotrimazole pessary 500mg*	Canestan	Pregnancy. Breast feeding. Children under 16.
	Fluconazole 150mg caps*	Canestan oral Diflucan	Adults over 60.

Warts & Verrucae	Bazuka Extra Strength Gel*	Veracur Verrugon	Diabetic patients
	Salactol Wart Paint*	Cuplex Duofilm Occlusal Salatac	Diabetic patients

*Indicates products available via HMR CCG Minor Ailment Scheme. If patients leave the Rochdale Borough all products may not be available elsewhere

NB – Clinicians retain the right to prescribe for any patient if they feel there is genuine clinical need or the patient is unable to access medicines required through the CCG Minor Ailments Scheme for any reason. Use of the [MAS] scheme can promote the role of community pharmacists and reduce the overall costs to the NHS through reducing primary care costs, dispensing fees and container allowances associated with provision of an NHS prescription

Appendix 2: May be insufficient evidence to prescribe

Category	Examples (N.B. this is not an exhaustive list)		Exceptions
Cough	Benylin cough products Codeine Linctus Covonia cough products Meltus Pholcodine Linctus Simple Linctus Sudafed cough products		None
Eye Care	Blephaclean Eye Lid Wipe Lid-Care Eyelid Wipe Optrex Supranettes RefreshOphth Soln 0.4ml Ud Ster Eye Cleansing Wipes		None
Health Supplements	Products containing glucosamine Products containing chondroitin. Products containing fish oils. Products containing co-enzyme Q10. Products containing Omega 7. Icaps, OcuVite, PreserVision Natures own, Natures aid		None
Herbal Remedies	St John's Wort, Heathaid, Kalms, Nytol, Bach flower remedies		None
Homeopathic remedies	Weleda products, Nelson products		None
Nasal Congestion	Menthol & Eucalyptus Inhalation Xylometazoline nasal (0.05% drops & 0.1% spray) Otradrops Otrivine (nasal drops & spray) Sudafed tabs & elixir Pseudoephedrine 60mg tabs Galpseud tabs & linctus Pseudoephedrine 30mg/5ml linctus		None
Probiotics	VSL#3		Pouchitis
Rubifacients	Algesal Balmosa Deep Freeze Mentholatum Radian B		None
Sore Throat	AAA Sore Throat Spray Difflam (Throat Spray & rinse) Covonia Throat Spray Dequadin Lozenges Ultra Chloraseptic Spray Dequaspray	Tyrozets Lozenges Merocaine Lozenges Strepsils Lozenges Merocet lozenges Bradasol Lozenges	None
Vitamins, Multivitamin & all mineral preparations (including Cod liver oil, Vitamin B products, Vitamin E products, , Vitamin A& D products)	Pharmacy own brands of vitamins/multivitamins (i.e. Boots, Lloyds, Superdrug, Valupak) Haliborange Santogen Fruitivits Sachets Spatone Seven Seas	Lamb Vita E Osteocaps Vega Osteocare Premier Redoxon Centrum Eye-Q Natravits	High dose vitamin D for proven Vitamin D deficiency. Thiamine for alcohol related conditions & neurological complications. Vitamin B12 deficiency. Forceval (post bariatric surgery). Vitamin supplements for premature babies as advised by hospital.

Appendix 3: May not be a clinical need to treat

Category	Examples (N.B. this is not an exhaustive list)	Exceptions NB: Follow GMMMG formulary <u>if there is a clinical need to treat</u>
Acne (mild)	Aluminium oxide 38.09% paste (including Bravisol paste no1) All Benzoyl Peroxide products (including Panoxyl , Brevoxyl Oxy, Acnecide products) Nicotinamide 4% Gel (including Freederm gel, Nicam gel) Quinoderm products	Moderate to severe cases where OTC products have failed (follow antibiotic guidelines). GM formulary products: Benzoyl Peroxide 5% cream, aquagel & gel. Benzoyl peroxide 10% /hydroxyquinoline sulphate 0.5% cream* (*Quinoderm 10% cream)
Dandruff (including cradle cap³)	Alphosyl 2 in 1 shampoo Capasal shampoo Ceanel concentrate shampoo Psoriderm scalp lotion T\Gel shampoo	Psoriasis
	Benzalkonium chloride 0.5% shampoo (including Dermax) E45 Dry Scalp shampoo Ketoconazole shampoo 2% (including dandrazol, ketopine, nizoral) Selsun shampoo	None
	Dentinox Cradle Cap Treatment Shampoo	None
Dental & Sore mouth Products <i>*If recommended by Dentist to be purchased or prescribed on dental prescription (both NHS & private)</i>	Duraphat Fluoride Toothpaste* : To be prescribed by Dentist	Use in Palliative Care: Chlorhexidine gluconate Mouth Wash, Benzylamine Mouthwash & Spray
	Sodium fluoride mouthwash, oral drops, tablets & toothpaste (including the brands: Colgate, En-de-Kay, Fluor-a day, fluorigard)*	
	Oraldene Mouthwash	
	Hydrogen Peroxide Mouthwash 6%* Peroxyl Mouthwash 1.5%,	
	Benzylamine Hydrochloride mouthwash & spray (including the brands: Difflam, Oroeze) *	
	Chlorhexidine gluconate mouthwash, oral spray & dental gel (including the brand Corsodyl)*	
Anbesol gel & liquid Bonjela products Iglu gel Rinstead pastilles	Use in Palliative Care: Bonjela gel	

³ Follow BNF advice: 'cradle cap in infants may be treated with coconut oil or olive oil applications followed by shampooing'.

Category	Examples (N.B. this is not an exhaustive list)	Exceptions NB: Follow GMMM formulary <u>if there is a clinical need to treat</u>
Emollients & bath/ shower products	Aveeno products, Dermacool products, Dermalo Bath Emollient, Dermamist Spray, Diprobath Emollient, Eucerin products, Neutrogena products	<ol style="list-style-type: none"> 1. Emollients only to be prescribed for patients with a confirmed diagnosis of significant skin disease (including eczema and psoriasis). 2. Patients discharged from a specialist centre on a particular product should be maintained on the same product if effective. <p>GM formulary products: Balneum cream, Balneum plus cream Dermol cream, Dermol 500 lotion, Dermol 600 bath emollient Doublebase Gel E45 cream ,E45 Emollient Wash Cream, Hydromol bath & shower emollient, Hydromol ointment(not cream) Oilatum Emollient</p>
	Balneum Products	
	Dermol 200 Shower Emollient, Dermol Wash	
	Doublebase products	
	E45 products	
	Hydromol products	
	Oilatum products	
Skin products	Bio-Oil Skin Care Oil Coconut oil Products containing Dexpanthenol (Bepanthen baby protective oint, Nivea SOS products) Flexitol products E45 foot & heel cream, Glucosamine gel SensetSkin Cleansing Foam Skin Salvation oint Vitamin E cream	None
Sunscreens	Ambre Solaire products Anthelios products Delph products Riemann P20 products Sunsense products Uvistat products	<p>Only to be prescribed within ACBS criteria: protection against ultraviolet radiation in abnormal cutaneous photosensitivity, resulting from genetic disorders or photodermatoses, including vitiligo and those resulting from radiotherapy; chronic or recurrent herpes simplex labialis.</p> <p>GM formulary products: Sunsense Ultra 50+ Uvistat 50</p>

Appendix 4 Example patient information sheet

Prescribing for clinical need policy – information for patients

Your doctor has provided you with this information sheet following a conversation you have had regarding prescriptions and their decision to decline your request for a specific treatment or Gluten Free Foods

About prescribing in Heywood Middleton and Rochdale

Medicines are an integral part of the health care that many patients rely on to manage their health conditions and over **3.6 million prescriptions** are written by local clinicians every year.

Local clinicians including GPs and hospital doctors as well as many others work to the Greater Manchester Formulary (see http://gmmmg.nhs.uk/html/formulary_bnf_chapters.html). This tool provides guidance on medicines that meet local and national guidance and are encouraged to be prescribed locally.

What is the prescribing for clinical need policy?

As well as these medicines, there are thousands of alternative or complementary treatments available on the market that some patients might find help manage their conditions.

In order to provide clear guidance for GPs about which of this extensive range of treatments should be prescribed on NHS prescriptions, local clinical commissioning groups have worked together with GPs, consultants, pharmacists, and patients and carers to agree that only those treatments that are clinically effective and provide a clear health benefit to patients should be prescribed on NHS prescriptions.

The resulting prescribing for clinical need policy has been adopted by all local GP practices in the area. This policy enables GPs to evaluate whether a treatment meets a patient's clinical need and therefore whether they should prescribe it.

What treatments are included in the prescribing for clinical need policy?

Many treatments and medicines have a clear evidence base that demonstrates that they are clinically effective and therefore will meet a patient's clinical needs. This includes most medicines prescribed by GPs to treat common conditions such as diabetes, asthma and high blood pressure.

What treatments are not included in the prescribing for clinical need policy?

- Some preparations do not meet clinical needs, such as antiperspirants, sunscreens, emollients, wart treatments and some gluten free products and are therefore not included.
- Other treatments including vitamins, ear wax removers, Chinese herbal medicines or homeopathic remedies do not have sufficient evidence of clinical benefits and are also not included.
- Finally, treatments for the symptoms of conditions, such as the common cold, sore throat and cough that would naturally resolve themselves, if untreated; and treatments for minor ailments, such as vaginal thrush, that can be treated in the pharmacy, are not included.

What happens if a treatment you would like is not included in this policy?

If a treatment you would like:

- Does not meet a clinical need or
- Does not have sufficient evidence of clinical benefit or
- If the condition would naturally resolve itself if untreated,

Local GP practices will not prescribe it on an NHS prescription.

For more information

The prescribing for clinical need policy has been agreed by all GP practices within HMR CCG. You can view the policy at :

If your condition changes please speak to your local pharmacist or GP.