



*Heywood, Middleton and Rochdale
Clinical Commissioning Group*

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

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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 undertook a consultation exercise in March 2016 and comments were considered by the Governing Body. Changes have been made to this policy in light of the responses received.

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 for funding 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 clear 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 suitably 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 and reduce the need for patients to attend A&E

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 effectively 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 (GMMM) 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, or marginally more costly to conventional (gluten containing) equivalents. In order to prioritise scarce NHS resources and ensure equitable treatments are available to all, HMR CCG proposes that the prescribing of Gluten Free (GF) Foods is restricted to staple foods and products such as those listed below will NOT normally be prescribed at NHS expense for any patient in HMR CCG

- Gluten Free Cakes
- Gluten Free Cake mixes
- Gluten Free Pizza bases
- Gluten Free biscuits

Additional dietary requirements should be achieved by choosing healthy foods which are naturally gluten free. **Specially manufactured Gluten free foods should provide no more than 15% total energy.** This means that usual healthy eating advice should be provided so that patients are aware that their gluten free products make up a relatively small proportion of their daily food intake

It is recommended that total carbohydrate should provide about 50% of energy intake. Non milk extrinsic sugars should not exceed 11% of energy intake.

¹ Advisory Committee on Borderline Substances

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

NB For children under 16 years of age – with confirmed diagnosis of Coeliac disease, prescribing should be based on the above policy, but the units supplied will be age –dependent. Refer to Coeliac Society or GMMMG guidance for the recommended units to be supplied monthly

Starches, intrinsic and milk sugars should therefore contribute about 39% of energy intake (DOH, 1991). Consumption of naturally gluten free foods such as potatoes and rice will also contribute to energy requirements.

For most patients – 8 units★ monthly of staple manufactured gluten free foods consisting of

- Bread (part baked) / Flour or Bread mix
- Pasta *
- Cereal or suitable alternatives

Would encourage patients to maintain a healthy balance of naturally + supplemented gluten free products, in line with national and regional recommendations.

Reference: Gluten Free Foods available on the NHS – Greater Manchester Medicines Management Group. <http://gmmmg.nhs.uk/docs/guidance/GMMMG%20Gluten%20Free%20Guidance.pdf>

★Units – are not containers – please refer to Page 6 of this document

HMR CCG formulary for Gluten Free (GF) products

Bread - Part baked (fresh bread to be prescribed only in **exceptional** circumstances due to potential for waste if not frozen and delivery costs). Part baked break typically has 2-3 months before the product is not fit for consumption

- White loaf
- Fibre loaf
- White rolls
- Fibre rolls

Bread Mixes & Flour

- Multipurpose bread mix
- Fibre bread mix
- Gluten Free Flour.

Pasta - Plain pasta only

- Spaghetti
- Lasagne
- Penne
- Spirals

Cereals

- Cornflakes
- Porridge / Oats

GPs are recommended to issue prescriptions for no more than EIGHT units monthly

The following guide will help Primary Care staff determine actual quantities to be issued on NHS prescription

Table 1: Number of units in each prescribable gluten-free food item

Prescribable food item	Number of units
400g bread/rolls/baguettes	1
500g bread mix/flour mix	2
250g pasta	1

Patients requesting items not on the above list should be directed to purchase these from supermarkets or other food outlets which supply Gluten Free products.

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 capsules	Anadin Mandanol Diprol Panadol Hedex Panadol Advance.	Long term conditions requiring regular pain relief.
	Ibuprofen 200mg tablets Ibuprofen 200mg caplets Ibuprofen 400mg tablets* Ibuprofen 100mg/5ml Susp*	Anadin Ibuprofen Mandafen Anadin Joint Pain Manorfen Anadin liquifast Nurofen Calprofen Orbifen Cuprofen Phor Pain Hedex	
	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 Mandanol 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.
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* Loratidine liquid 5mg in 5ml Cetirizine 10mg tablets Cetririzine oral solution 1mg / ml	Clarityn Allergy tabs Clarityn Rapide tabs Piriton tablets and clquid	Children under 2 yrs. Children 2-12 years weighing less than 30kg. Pregnancy. Breast feeding.
Cold sores	Aciclovir cream 5%*	Cymex Ultra Virasorb Lypsyl Zovirax Vectavir	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
Constipation	Senna Tablets Ispaghula sachets Lactulose	Senokot Fybogel	Patients under 12 years of age. Confirmed need for long term use as a result of ongoing need or underlying pathology
Cough	Pholcodine Linctus Simple Linctus Simple Linctus Paediatric		None
Diarrhoea	Dioralyte sachets* Electrolade sachets*	Dioralyte Relief	None
	Lopermide caps 2mg*	Diah-limit Imodium Diaquitte Norimode Diocalm Ultra Normaloe Entrocalm	Children under 12 years. Inflammatory bowel disease. Post bowel surgery. Post pelvic radiation. Colorectal cancer.
Hay fever	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	Children under 12 years. Patients with kidney problems. Pregnancy. Breast feeding. Children under 12 years. Pregnancy. Breast feeding.
	Chlorphenamine 4mg tabs*	Allercalm Piriton tabs 4mg Hayleve Pollenase tabs Piriton Allergy tabs 4mg	Children under 12 years. Patients with kidney problems. Pregnancy. Breast feeding. Children under 12 years. Pregnancy. Breast feeding.
	Chlorphenamine oral solution 2mg/5ml(sugar free)* Chlophenamine 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

	Treatment	Other brands to be aware of (N.B. this is not an exhaustive list)	Exceptions
	Malathion Aqueous Lotion 0.5%*	Derbac-M Liquid 0.5%*	Babies under 6 months.
Head Lice	Dimethicone Lotion 4% *	Hedrin* Linicin Lyclear Mousse Lyclear Repellant Nitrid Spray Nyda Spray	Babies under 6 months.
Indigestion / Heartburn	Gaviscon Advance tabs* Gaviscon Advance liquid* Peptac Liquid	Gaviscon 250 tabs Gaviscon Cool (tabs & liquid) Gaviscon Double Action (tabs & liquid)	Children under 16 years
	Magnesium Trisilicate Mixture		Children under 16 years.
	Ranitidine 75mg tablets	Zantac	Children under 16 years of age
Infant colic	Infacol Suspension 40mg/ml S/F*,	Dentinox Infant colic drops	None
Nappy rash	Metanium* Sudocrem* Permethrin 5% dermal cream*	Bepanthen Drapolene Morhulin Zinc & Castor Oil Lyclear Lythrin	Babies under 2 months.
Nasal congestion	Sodium Chloride 0.9% Nasal Drops* Xylometazoline Nasal Drops 0.05% Xylometazoline 0.1% Nasal Spry	Snufflebabe nasal drops Calpol Soothe & Care (nasal drops & spray)	Pregnancy.
Teething	Ibuprofen suspension 100mg in 5ml	Nurofen suspension	Babies under 2 months of age
	Bonjela Teething Gel*	Anbesol teething gel Calgel teething gel Dentinox (teething gel & toothpaste)	Babies under 2 months of age
	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*	Ovex	Under 2 years. Pregnancy. Breast feeding.

	Mebendazole 100mg chewable tablet	Ovex	Under 2 years. Pregnancy. Breast feeding
Vaginal thrush	Fluconazole 150mg caps*	Canestan oral Diflucan	Pregnancy. Breast feeding. Children under 16. Adults over 60. Diabetic patients
	Clotrimazole cream 1%* Clotrimazole pessary 500mg Clotrimazole combi-pack (2% cream and 500mg Pessary)	Canestan	

*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.

A review of the medicines available under the scheme will be undertaken by December 2106

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 Diffiam (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 GMMMG 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>

Prescribing for clinical need policy – information for patients

Your doctor may provide you with this or a similar information sheet following a conversation you have had regarding prescriptions and their decision to decline your request for a specific treatment or Gluten Free (GF) 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 HMR CCG Website at <http://www.hmr.nhs.uk/index.php/publications/policies-and-guidelines>

If your condition does not improve please speak to your local pharmacist or GP.