

Questions and Answers on prescribing gluten free foods, medicines for self-care and restricted use (non-formulary) medicines

Policy Content

What are the new policies on prescribing gluten free foods, medicines for self-care and restricted use (non-formulary) medicines?

Gluten Free Foods

Mansfield & Ashfield and Newark & Sherwood CCGs do NOT support the supply of Gluten Free Foods on NHS prescription

Medicines for Self-care

As part of its self-care strategy, Mansfield & Ashfield and Newark & Sherwood CCGs do NOT support the prescription of medicines and treatments for minor, short term conditions where:

- self-care is the most appropriate route
- medicines and treatments are available to buy over the counter

All prescribers within Mansfield & Ashfield and Newark & Sherwood CCGs, including GPs and non-medical prescribers, should not prescribe readily available over-the-counter medicines.

Restricted Use medicines

Mansfield & Ashfield and Newark & Sherwood CCGs do NOT support prescribing of the following medicines:

- Medicines not included in the Nottinghamshire joint formulary.
- Medicines classified as Grey or Red under the Nottinghamshire APC Traffic Light system.
- Branded medicines where a lower cost generic is available.
- Medicines included on the local *target list** due to high cost and/or usage outside the recommended indications.

NB: Where patients are already receiving treatment that is not recommended locally, these will be managed on a case by case basis to avoid patients being adversely affected by this policy.

The full prescribing policies are posted on the clinical pathways website - <http://midnottspathways.nhs.uk/GetCategory/?mid=1122&category=Medicines+Management+%2f+Prescribing> . The policy statements are also on both CCG websites.

Where there are no special circumstances, prescribers are directed NOT to prescribe the medicines/foods within the policies.

Special cases

What constitutes a special case or 'special circumstances'?

It is difficult to define 'special circumstances' before they have been identified. A CCG process is being agreed using the Individual Funding Request (IFR) policy as a standard. The draft policy includes the following guidance:

In order to be able to consider whether a patient has special clinical circumstances the following issues should be considered:

- Are there any clinical features of the patient's case which make the patient significantly different to the general population of patients with the condition in question at the same stage of progression of the condition?
- Would the patient be likely to gain significantly more clinical benefit from the requested intervention than might be normally expected for the general population of patients with the condition at the same stage of the progression of the condition?

The implications of this approach are that if a patient can be seen to be part of a group of patients for whom a treatment is not made available by the CCG under the CCGs existing policies then special clinical circumstances for this individual patient are unlikely to be demonstrable.

The special case should consider requests for treatments that are not routinely available based on the patients clinical circumstances. This means that **social and personal factors such as age, gender, education, caring responsibilities and family circumstances can only be taken into account where they are relevant to the patients clinical outcome.** Whilst a patient's professional, economic or social standing or their family responsibilities are important to individuals, the CCG policy is that they are not relevant in assessing whether a patient has special clinical circumstances.

What is the Referral process for special cases? This will be included in the draft policy, and will be similar to the IFR process.

In summary,

- The Clinician will complete a standard request form and send to a designated CCG officer (TBC)
- The request will be triaged,
- A panel discussion will be held if required
- The clinician and patient will be notified of the decision
- An appeals process will be developed - details to be confirmed.

What will the turnaround time be for the central assessment process to reach a decision about a patient?

The plan is to have a weekly triage process and hold a panel meeting every 2 weeks as necessary, so the turnaround should be 1-3 weeks.

Can the patient continue to be prescribed the medicine whilst they await the outcome of a committee decision?

This is likely to be case dependent.

If a patient is currently prescribed the medicine, then a plan should be put in place to review it. This plan can include referral to the special case panel, patient complaint etc. and discussion around prescribing options should be agreed alongside it. In most cases where the patient has received the medication long term, it will be appropriate to continue prescribing until a decision is made.

Complaints

How can patients complain about these changes to policies?

The CCG is encouraging all patient complaints to be managed through the Patient Experience Team, unless it is a simple task of reassuring the patient about a prescription change.

Our main aim of having the central complaints and 'special case' process are to prevent staff getting too overwhelmed, and allowing a level of consistency across the patch.

Also, we can collectively see trends in the data, such as No. of patients, concerns raised, practice referrals etc. This will help the CCG take collective action or provide further advice to prescribers/patients as required.

Has the CCG communicated with community pharmacists and secondary care colleagues on the new policies?

Community pharmacists, optometrists and dentists received communications around this policy on Friday 3 March 17. The CCG are also planning to include awareness on the new policies into upcoming community pharmacy training events.

Secondary care has been informed of the policies. Meetings have taken place with SFH and NHCT. NUH has discussed this at their Drug & Therapeutics Committee meeting. Chief Pharmacists have been asked to disseminate the message to their teams. In SFH, Steve May, Chief Pharmacist agreed to ask divisional pharmacist to discuss in their respective areas.

Communications have also gone out to community nurses, dieticians and podiatrists, and a meeting took place with the Deputy Chief Nurse in Local Partnerships on 24th March.

Can people with pre-payment certificates still receive prescriptions for products covered by these policies'?

No. The policies apply to all patients.

Patient can apply for a refund on pre-payment certificates. Further information is available here: <http://www.nhsbsa.nhs.uk/HealthCosts/2132.aspx>

Although not specifically included on the webpage, patients can request a refund in these circumstances by sending a covering letter explaining the change of policy, including their personal details and their pre-payment certificates.

For 3 month certificates, the patient would have to apply in the first month, therefore any specific cases may need to be referred to the CCG for consideration.

Where do prescribers stand legally if a patient is "able but not willing" to accept OTC / medicines approved for local use?

Legal advice has been sought on whether the prescribing policies breach GMS Terms of Service. Although ultimately the decision to prescribe an item remains with

the prescriber, the prescribing policies are considered to be lawful and would not breach the GMS terms of service on the following grounds:

- The GMS terms of service state that the GP has to prescribe a medication where the GP considers the medicine to be 'needed.' It is argued that where the patient is able and willing to obtain their medicine from alternative route (i.e. community pharmacy, supermarket or a supply of an alternative product), a decision not to prescribe does not breach the GMS terms.
- Furthermore, GMS regulation 64 prohibits excessive prescribing in relation to cost. Prescribing in these circumstances can be viewed as excessive (and therefore in breach of the GPs terms of service) as the medicine is available by an alternate and appropriate route.
- In all cases, prescribers should keep clear and comprehensive notes and use clinical discretion where they deem that there is a clinical 'need' to prescribe.
- The CCG policy must include scope to permit discretion in special clinical circumstances.

The legal advice makes it clear that prescribers do not need to issue a prescription unless there is a clinical need to do so. Prescribers are not obliged to provide an FP10 unless their assessment of the patient's clinical 'need':

1. Cannot be met in any other way

And

2. The 'need' is met by a response from the prescriber that is proportionate, i.e. avoids an 'excessive' response (including excessive cost.)

Notes

- In a situation where a patient refuses the advice to purchase a medicine i.e. they are apparently not 'willing'; an assessment of whether (in an otherwise rational person) this refusal is 'reasonable' would be appropriate. In such circumstances a refusal to meet the 'need' via a FP10 on the grounds that this would be 'excessive' would be reasonable (and defensible in law).
- Refusal of treatment is every patient's human right and does not 'entitle' the individual to an alternative treatment.
- It is (legally) appropriate for the CCG to define the limits of the 'needs' that will be addressed by the NHS where there is an appropriate alternative route for those 'needs' to be met.
- Whilst the law can be clearly defined, this policy will still be subject to clinical discretion. The CCGs will assess of prescribing trends to highlight practices that are using too much discretion, and may benefit from further advice and support for themselves and their patients.

Can message relating to the polices be added to the GP computer system eg through OptimiseRx?

Yes. The restricted use medicines policy uses APC policy, and therefore messages should already be included. A message around gluten free products will be added. Information on OTC medicines is not very suitable to include on OptimiseRx, as OTC medicines are also used for long-term conditions, prescribers may want to avoid constant firing of messages around LTC treatment. Therefore a formulary message may be more appropriate.

Policy Specific Questions

Gluten free

What communication material is available to help implement the policy?

A policy statement and brief leaflet has been developed and circulated electronically to all practices.

In addition practices may choose to place the policy statement on their own website. A template covering letter has also been circulated. Practices can adapt as appropriate to inform patients that currently have GF products prescribed of the policy change.

The CCG is also developing content for a webpage to offer support to patients on managing a gluten free diet. This will provide some general information and signpost patients to useful resources.

Does the cessation of gluten free prescribing include children? Yes.

When is the final cut off for issuing of gluten free foods on FP10.

The cut off is the 31 March 2017, however practices must ensure that patients only receive the correct monthly amount e.g. 8 units during March.

Children may have up to the number of units appropriate to their age as per the national coeliac prescribing guidelines during March.

Self-care

Is there a list of appropriate self-care conditions? Yes. This is included in the written policy.

See: <http://midnottspathways.nhs.uk/GetCategory/?mid=1122&category=Medicines+Management+%2f+Prescribing>

What communication material is available to help implement the policy and how will the information be communicated to patients?

Patient information including leaflets and posters have been produced and emailed to practices. Copies are being printed and will be circulated to Pharmacies, GP Practices and displayed in various public locations. Practices are also advised to communicate the messages, including Pharmacy First to patients – eg via Text, triage through reception staff, in-practice videos etc.

Which medicines can be bought Over-the-Counter (OTC)?

A list of common medicines available OTC has been emailed to practices to provide information to GPs and prescribers on the range of medicines that can be purchased.

Are there restrictions to OTC medicines? Yes, like prescribed medicines, OTC medicines have product licenses that determine which indication, dose and quantity are available for OTC use. This information is too complicated to include in the OTC list, therefore practices are encouraged to liaise with their local community pharmacy for further information.

Can Patients buy more than 32 tablets of Paracetamol?

Paracetamol and aspirin in non-effervescent tablet or capsule form can be bought in quantities of up to 100 (NB: in reality 96; 3 x 32) under a Pharmacist's supervision, where it is in the patient's best interests.

There are no legal limits on the quantity of over the counter effervescent tablet, granule, powder and liquid preparations of paracetamol and aspirin that can be sold to a person at any one time but Pharmacists will exercise professional judgment on what quantity to supply.

What is Pharmacy First?

Pharmacy First is a minor illness scheme funded by NHS England that is available for children and people who don't have to pay for their prescriptions. Eligible patients can get free over the counter treatment from Pharmacies for a range of common minor illnesses, such as fever, head lice and hay fever.

The 'Pharmacy First' service is now available in most local Community Pharmacies. The local pharmacist can offer expert advice and medicines for a wide range of common ailments without the need to visit the GP. No appointment is necessary but the patient will need to give the pharmacist their NHS number, or child's NHS number to receive advice and, where appropriate, medicines free of charge. Further information is available at: <http://psnc.org.uk/nottinghamshire-lpc/nhs-england/northmidlands/pharmacy-services/pharmacy-first-scheme/>

Are people with pre-payment certificates eligible to use Pharmacy First? Yes

Are their limits on Pharmacy First?

Yes, there is a specified formulary covering common conditions and medicines only. Patients are allowed to seek advice and treatment up to twice a month for the same condition.

Does the self-care policy cover longer term conditions? Long term conditions are excluded from the policy and NHS prescriptions should still be provided for these conditions.

Are pregnant / breast-feeding women expected to buy OTC too? Yes. The Pharmacist can give advice on what to buy or refer to the GP if required. Where a GP recommendation is required for Pharmacists to supply a medication, then patients may need to see the GP first before being referred to the Pharmacist.

Is hay fever a long term condition? Hay fever is classed as a minor illness that can be managed using OTC treatment. Therefore this is not routinely classed as a LTC, unless it requires more complex treatment that is not available OTC.

When does a minor ailment become a chronic issue? This is difficult to answer as it would be assessed on a case by case basis. The question to ask is whether the condition can be managed effectively using OTC medicines and advice.

Does the policy apply to care home patients, housebound and children in schools who may need labelled medicines to support administration?

In principle, the policy applies to all patients, so workable solutions will need to be agreed to ensure that everyone is treated equitably under the policy.

In care homes, homely remedy policies would negate the need for labelling. Further advice can be sought via the prescribing team.

Is there a specific list of indications for which OTC meds can be prescribed on FP10?

The self-care policy encourages clinicians to refer patients who have a specific minor illness to Pharmacies for advice and treatment. The policy purposely avoids reference to medicines as this should be discussed between the Pharmacist and patient, and it also avoids the risk of prescribers recommending medicines that are not licensed for OTC use for a particular condition.

What if a patient is advised to take a dose which is not an OTC dose?

Community Pharmacists cannot sell OTC medicines outside their license. Therefore patients should continue to receive NHS prescriptions for any medicines (inc higher doses) that are not available OTC.

Non formulary / restricted use medicines

How does the restricted use medicine policy link to Nottinghamshire APC policy?

The CCG restricted use medicines policy is a tool to implement APC policy more completely, and prevent new non-formulary prescribing of medicines. It is therefore directly aligned to APC policy.

What communication material is available to support implementation of the policy?

A template letter has been developed to support practices in referring new requests for non-formulary medicines back to secondary care. Template medicines switch letters will be developed to undertake the review of existing medicines.

What is the process for review of grey and red drugs under the restricted use medicines policy?

Initially, the restricted use medicines policy aims to prevent new non-formulary treatment being started.

A target list of non-formulary medicines (included high cost brand) is identified, based on their relative cost, and / or usage. Patients on these medicines will be reviewed by the GP/prescribing team, and special cases considered.

Over time, the majority of patients on long term treatment will be switched, unless there are clear clinical grounds to retain the current treatment. Alternative medicines will be agreed with the practice and/or specialist as required. Some changes may include re-referral to an NHS consultant, discussion with then local specialist, or referral to the APC / interface pharmacist. The ultimate aim is to review all patients, but review will be prioritised to make the best use of the team's time, so full implementation will take time.

Secondary care will also be given this target list and communication will also be sent to community pharmacists so they are aware of the work being undertaken, Wherever possible, the community pharmacist should be notified before any switch in case there are any stock-holding issues.

What is the process if the patient refuses formulary treatment and there are not special clinical circumstances to warrant treatment?

This situation may be handled in two ways:

1. If a patient requests a particular restricted use product, despite local NHS policy not to prescribe the item, the GP may issue a private prescription and must note the following:
 - If a suitable alternative formulary product is available but the patient has declined the offer of an NHS prescription, this should be clearly documented in the patient notes.
 - The prescriber must NOT levy a charge for the issue of a private prescription under these circumstances
2. If a patient refuses formulary treatment and does not wish to have the medicine prescribed privately, then they should be directed to through the complaints process.

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