Hertfordshire and West Essex Integrated Care System

NHS Hertfordshire and West Essex Integrated Care Board

For use in South and West Hertfordshire

Guidance Brief

Gluten Free Food on prescription

November 2017 (updated January 2019)

In this briefing

Background

Definitions

Procedures

Consequences

National guidance

Click on the following link to access the national guidance: https://www.nice.org.uk/guidance/ng20 (September 2015)

Further information

The full guidance can be found on: http://hertsvalleysccg.nhs.uk/ and/or please contact Head of Pharmacy and Medicines Optimisation (PMO).

Background

Historically, gluten free products were added to the list of products available on NHS prescriptions when they were not easily available for people to purchase.

Now there is a wide range of gluten free products available from supermarkets, the internet and health food stores along with local pharmacies that are sold at prices that are considerably lower than the NHS is charged when bought for use on prescription. In addition to these products, there is also a wide variety of naturally gluten free food including; rice, fresh fruit and vegetables, meat, poultry, fish, cheese and eggs.

All individuals will now be expected to purchase gluten-free foods, including groups that currently receive free prescriptions (such as children, elderly and those on low incomes) from supermarkets, pharmacies, on-line or other shops

Patients with metabolic conditions will continue to be allowed to have prescribed products because these cannot easily be purchased. This is mentioned because some of these products are both low protein and low gluten.

Definition

Coeliac Disease

Coeliac disease is a lifelong autoimmune disease caused by a reaction to gluten. Once diagnosed, it is treated by following a gluten-free diet for life[1].

Dermatitis Herpetiformis

This is a skin manifestation of coeliac disease[1].

Gluten

Gluten is a protein found in wheat, rye and barley.

Procedures to be followed

1. Herts Valleys CCG will promote the purchasing of gluten free foods with the exception of patients with learning disabilities without a carer to aid in managing a gluten free diet or where there are safeguarding concerns. People who are deemed an exception to this guidance will be entitled to 8 units/month (9 units/month if in third trimester of pregnancy and 13 units/month if breast-feeding) of gluten free mixes and bread products (this excludes part-baked bread) listed in the Drug Tariff, as per the Amendment Regulations from 1st December 2018. The number of units is in line with Herts valleys CCG gluten free guidance issued in June 2016.
2. For people who are not an exception to this guidance but where a GP believes a gluten free product should be prescribed rather than purchased, a *Double Red Drug Request* form should be completed and submitted to the Herts Valleys CCG Pharmacy & Medicines Optimisation Team for consideration.

People who are deemed exceptional to this guidance (as outlined above) will be restricted to the following:

- Table 1: Recommended units for prescribing per month.

All patients (children and adults)	8 units
Breastfeeding	12 units
3rd trimester pregnancy	9 units

- Table 2: Number of units per prescribable food item

400g fresh or long-life bread	1 unit
500g bread/flour mix	2 units

The number of units listed above are in line with Herts Valleys CCG gluten free guidance issued in June 2016.

Consequences of a breach

Breaches of this guidance could lead to:

- Failure of delivery of financial balance
- Wastage of limited NHS resources
- Complex patients are not attended to as rapidly as they could be

References

1. Coeliac UK. Website accessible via https://www.coeliac.org.uk/home/ [Accessed October 2017]

Checklist for the Review and Approval of Procedural Documents

To be completed and attached to any document which guides practices when submitted to the appropriate committee for consideration and approval.

	Yes/No/ Unsure	Comments
Title of Document		
Could this guidance be incorporated within an existing guidance?	N	
Does this guidance follow the style and format of the agreed template?	Y	
Has the front sheet been completed?	Y	
Is there an appropriate review date?	Y	
Does the contents page reflect the body of the document?	Y	
Are there measurable standards or KPIs to support the monitoring of compliance with and effectiveness of the document?	Y	
Are all appendices appropriate and/or applicable?	Y	
Have all appropriate stakeholders been consulted?	Y	
Has an Equality Impact Assessment been undertaken?	Y	
Is there a clear plan for implementation?	Y	
Has the document control sheet been completed?	Y	
Are key references cited and supporting documents referenced?	Y	
Does the document identify which Committee/Group will approve it?	Y	

Is there an implementation plan for this guidance?	Y	

Individual Approval			
If you are happy to approve this document, please sign and date it and forward to the chair of the committee/group where it will receive final approval.			
Name	Charlotte Earl	Date	25th January 2019
Signature			

Committee Approval			
If the committee is happy to approve this document, please sign and date it and forward copies to the person with responsibility for disseminating and implementing the document and the person who is responsible for maintaining the organisation's database of approved documents.			
Name	Thelma Stober	Date	
Signature			

GLUTEN FREE FOOD ON PRESCRIPTION

Version Number	1.1
Ratified By	Herts Valleys CCG Board
Date Ratified	9th November 2017 (update ratified 24th January 2019)
Name of Originator/Author	Pharmacy & Medicines Optimisation Team
Responsible Director	Lynn Dalton
Staff Audience	Herts Valleys CCG
Date Issued	November 2017 (re-issued January 2019)
Next Review Date	November 2021

DOCUMENT CONTROL

Plan Version	Page	Details of amendment	Date	Author
1.0		Guidance ratified by Herts Valleys CCG Board	09/11/17	Pharmaceutical Advisor, PMOT
1.1		Reviewed and updated in line with national guidance and ACBS Amendment Regulations	31/12/18	Pharmaceutical Advisor, PMOT

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1. INTRODUCTION

Gluten free products will no longer be available routinely on prescription as part of prioritising services offered within the Clinical Commissioning Group (CCG) to provide maximum healthcare value within the finances available. This allows for reallocation of funding from areas assessed as being of lower value to services which would provide the greatest possible benefit to the population as a whole.

2. PURPOSE

Historically, gluten free products were added to the list of products available on NHS prescription when they were not easily available for people to purchase.

Now, there is a wide range of gluten free products available from supermarkets, the internet and health food stores along with local pharmacies. Some products are sold at prices that are considerably lower than the NHS is charged when bought for use on prescription. In addition, people with coeliac disease can follow a gluten free diet without needing to have specially formulated gluten free foods. There are a wide variety of naturally gluten free foods including; rice, fresh fruit and vegetables, meat, poultry, fish, cheese and eggs.

People diagnosed with coeliac disease or dermatitis herpetiformis should be identified and gluten free products on NHS prescriptions stopped.

People without a definite diagnosis of the above should not be receiving gluten free foods on NHS prescription.

Intended outcomes of the proposal is that all individuals will now be expected to purchase gluten free foods, including groups that currently receive free prescriptions (such as children, elderly and those on low incomes) from supermarkets, pharmacies, online or other shops.

This guidance should not be used for people with learning disabilities who do not have a carer to help manage their diet, or where there are safeguarding concerns, e.g. a patient who has explicitly tried, but failed, to follow the gluten free diet due to comprehension issues such as English not being their first language. This guidance does not apply to patients on a low protein diet (also low gluten products) because of metabolic diseases.

For people who are not an exception to this guidance (as described above) but where a GP believes a product should be prescribed on a repeated basis rather than purchased, a *Double Red Drug Request* form may be completed and submitted to Herts Valleys CCG Pharmacy and Medicines Optimisation Team for consideration of approval for on-going prescribing. It is important to

note that no additional funding for prescribing will be provided. This process is being put into place so that contentious cases can be discussed and to improve the consistency between practices with implementing this guidance.

People who are deemed exceptional to this guidance will be restricted to the following:

- Table 1: Recommended units for prescribing per month.

All patients (children and adults)	8 units
Breastfeeding	12 units
3rd trimester pregnancy	9 units

- Table 2: Number of units per prescribable food item

400g fresh or long-life bread	1 unit
500g bread/flour mix	2 units

The the number of units listed above are in line with Herts Valleys CCG gluten free guidance issued in June 2016.

3. DEFINITIONS

Clinical Exceptionality
A patient who has *clinical* circumstances which, taken as a whole, are outside of the range of clinical circumstances presented by a patient within the normal population of patients with the same medical condition and at a similar state of progression.

Coeliac Disease
Coeliac disease is a lifelong autoimmune disease caused by a reaction to gluten. Once diagnosed, it is treated by following a gluten free diet for life[1].

Dermatitis Herpetiformis
This is a skin manifestation of coeliac disease[1].

Gluten
Gluten is a protein found in wheat, rye and barley.

4. ROLES AND RESPONSIBILITIES

4.1 Roles and responsibilities of clinicians managing the care of Herts Valleys CCG patients

All clinicians with the responsibility for the care of Herts Valleys CCG patients should ensure that they are aware of the contents of this guidance. This includes a requirement to review the contents and assess the relevance in managing the care of their patients.

4.2 Roles and responsibilities of Herts Valleys CCG staff

All Herts Valleys CCG staff should ensure that they review the contents of this guidance and assess the relevance to their role. Herts Valleys CCG will provide additional information resources to practices. These resources will be available to be downloaded from the Herts Valleys CCG website. The guidance will also be available in the public domain.

4.3 Consultation and Communication with Stakeholders

A national consultation about the availability of gluten free products on NHS prescription closed in June 2017. Outcomes can be found at the following link: https://www.gov.uk/government/consultations/gluten-free-foods-on-nhs-prescription.

Following a local, public consultation (6th July – 14th September) and a meeting to discuss the concerns of the patient advocacy groups in September 2017, East & North Herts and Herts Valleys Clinical Commissioning Groups no longer support prescribing of gluten free foods. Nine representatives of Coeliac UK, and other patient advocacy groups attended to represent the coeliac population; Chief Executive Officers of both Herts Valleys and East and North Herts CCGs; Head of Pharmacy and Medicines Optimisation (PMO) of both CCGs and Head of Communications for Herts Valleys CCG all were present to listen to concerns raised.

This guidance will be uploaded to the Herts Valleys CCG website. The CCG will provide information resources to aid GPs in implementing this guidance.

5. CONTENT

Coeliac disease is a common digestive condition where the small intestine becomes inflamed and unable to absorb nutrients. Exposure to gluten (which is found in wheat, barley and rye) may result in a number of symptoms and adverse effects ranging from mild to very severe[2].

Coeliac disease is believed to be present in up to 1 in 100 of the population although only about 24% of people with the condition are clinically diagnosed[1]. Coeliac disease may be diagnosed at any age[2,3]. Reported cases of coeliac disease are higher in women than men[2].

The health risks linked to untreated and poorly managed coeliac disease include: osteoporosis and increased risk of bone fractures; infertility and adverse outcomes in pregnancy; and some types of cancer. Coeliac disease is managed by excluding foods that contain gluten from the diet. There are no medicines available to treat the condition, and it cannot be cured. Adults and children with confirmed coeliac disease must adhere to a life-long diet that excludes gluten[1,2,3].

When people diagnosed with coeliac disease adhere to a strict gluten free diet, most will be restored to full health and will be protected against developing long-term health complications. The law requires that foods labelled ‘gluten free’ can contain no more than 20 parts per million of gluten. For most people

with coeliac disease trace amounts of gluten will not cause a health problem. However, there are a minority of people with coeliac disease who are unable to tolerate even trace amounts of gluten[1,2].

A gluten-free diet therefore necessitates an avoidance of some foods. Many basic foods, such as meat, fish, fruit, vegetables, cheese, milk, butter, potatoes and rice are naturally free from gluten[1,3], and rice, corn, soy and potato (gluten free) flours are also available.

There are many gluten free products and alternatives to cereal based foods are widely available in corner shops, pharmacies, supermarkets and health food shops. However, the substitute products are generally more expensive than carbohydrate staples that contain gluten. Many gluten free products provided on prescription through community pharmacists are also available to buy from supermarkets or the pharmacy itself.

Research by the Food Standards Agency to investigate the nutritional adequacy of a gluten free diet for people with coeliac disease concluded that currently there is no robust evidence to show that individuals with coeliac disease adhering to a gluten free diet experience any nutritional deficiency. There was also no firm evidence to show that individuals following a gluten free diet had an inadequate intake of iron, calcium, and B vitamins[4].

Limited evidence is available regarding the factors associated with non-adherence to a gluten free diet. A search of the literature found one systematic review[5] which sought to establish the factors that enable people with coeliac disease to adhere to a gluten-free diet. The researchers appraised 10 studies from the international literature (two studies were conducted in a UK setting) and concluded that the evidence for factors associated with non-adherence to a gluten free diet is of variable quality.

Support for patients

Patients with coeliac disease are entitled to request an annual review with their GP.

Patients with a confirmed diagnosis of coeliac disease should understand their condition and be provided with information about a gluten free diet (Coeliac UK's website: http://www.coeliac.org.uk is a useful resource).

6. MONITORING COMPLIANCE

Providers will be audited as per the Terms of Reference within their Herts Valleys CCG contracts for compliance to the guidance.

The impact of the guidance will be monitored by using electronic prescribing data, patient feedback and comments.

7. EDUCATION AND TRAINING

Clinicians managing the care of Herts Valleys CCG patients, and Herts Valleys CCG staff need to be aware of this guidance and its implications.

For exceptionality, the *Double Red Drug Request* process is to be used; clinicians should make themselves familiar with the process.

8. REFERENCES

1. Coeliac UK. Website accessible via https://www.coeliac.org.uk/home/ [Accessed October 2017]

2. NHS Choices. Coeliac Disease. Website accessible via: https://www.nhs.uk/Conditions/Coeliac-disease/Pages/Introduction.aspx. [Accessed October 2017]

3. National Institute for Health and Care Excellence (NICE). *Coeliac disease (NICE guideline NG20)*. 2015. Accessible via: https://www.nice.org.uk/guidance/ng20

4. Foods Standards Agency. *Literature review of the nutritional adequacy of a typical gluten-free diet.* 2015. Website accessible via: https://www.food.gov.uk/science/research/allergy-research/t07053 [Accessed October 2017]

5. Foods Standards Agency. *Systematic review on tolerable levels of gluten for people with coeliac disease.* 2014. Website accessible via: https://www.food.gov.uk/science/research/allergy-research/t07048 [Accessed October 2017]

6. NHS England. *Prescribing Gluten-Free Foods in Primary Care: Guidance for CCGs*, November 2018. Website accessible via: https://www.england.nhs.uk/wp-content/uploads/2018/11/prescribing-gluten-free-foods-primary-care-guidance-for-ccgs.pdf [Accessed December 2018]

Appendix 1 - Equality Analysis – Full Equality Impact Assessment

Title of guidance**, service, proposal etc. being assessed:**

guidance for the Commissioning of gluten free foods

What are the intended outcomes of this work?

The CCGs are considering that GPs will stop the routine prescribing of gluten free foods.

The outcomes of the proposal to patients is that all individuals will now be expected to purchase gluten free foods, including groups that currently receive free prescriptions (such as children, elderly and those on low incomes) from supermarkets, pharmacies, on-line or other shops. The guidance excludes people with learning disabilities who do not have a carer to help manage their diet and where there are safeguarding concerns.

How will these outcomes be achieved?

The CCGs will promote the purchasing of gluten free foods where possible to reduce unnecessary costs to the NHS.

Who will be affected by this work?

The guidance applies to all patients except for those with learning disabilities who do not have a carer to help manage their diet and if there are safeguarding concerns.

Evidence

What evidence have you considered?

Against each of the protected characteristics categories below list the main sources of data, research and other sources of evidence (including full references) reviewed to determine impact on each equality group (protected characteristic).

This can include national research, surveys, reports, research interviews, focus groups, pilot activity evaluations or other Equality Analyses. If there are gaps in evidence, state what you will do to mitigate them in the Evidence based decision making section of this template.

It is reported that approximately 1% of the population have coeliac disease and this proposal will only affect people receiving prescriptions for gluten free food. A recent review of 56% of practices in the East and North Hertfordshire CCG area showed an average prevalence of 0.33% of coded coeliac patients of which an average of 45% (range 22-75%) received repeat prescriptions for gluten free foods (total number of

coeliac coded patients = 1360 and number of patients coded with gluten free products on prescription = 611).

In order to be transparent regarding the proposed changes the CCGs consulted the public for a 10 week period including patient groups, stakeholders and other interest groups.

Other neighbouring CCGs such as Bedfordshire and Milton Keynes have policies which suggest that all gluten free products on prescription are low priority and should not be recommended. Many CCGs restrict gluten free prescribing by quantities and or by types of items. Currently the access to gluten free food on prescription across Hertfordshire is more restricted in HVCCG compared with ENHCCG; HVCCG restrict items to eight units of essentials only (e.g. bread and flour mix).

In the East and North Hertfordshire CCG area the quantities allowed are larger and consequently there currently is a higher current usage and spend.

Clearly the result of different CCGs having different policies is inequitable, as patients in different localities may have different access. We are attempting to have a county-wide approach which we hope will improve equity within Hertfordshire.

Age

Patients will not receive prescriptions for gluten free foods.

Currently, you can get free NHS prescriptions if, at the time the prescription is dispensed, you:

- are 60 years or over
- are under 16 years
- are 16-18 years and in full-time education

People with coeliac disease amongst these groups would therefore have to pay for gluten free food, which could impact income or their management of their condition.

However there could be a negative impact on elderly / housebound / disabled people who do not have access to the internet or to shops where gluten free foods to purchase are stocked.

Mitigating actions:

The care of the individual patient must remain a prescribers first concern as described in the GMC ‘duties of a doctor’

http://www.gmc-uk.org/guidance/goodmedicalpractice/dutiesofadoctor.asp

Therefore the prescriber should recommend treatment based on clinical need and if there are concerns about an individual patient's safeguarding issues the GP may prescribe.

Disability

Currently, patients can get free NHS prescriptions if, at the time the prescription is dispensed, they:

- have a continuing physical disability that prevents them from going out without help from another person and have a valid MedEx
- hold a valid war pension exemption certificate and the prescription is for an accepted disability

People with coeliac disease, amongst these groups of people, may therefore be negatively impacted as a result of this proposal.

Gender reassignment (including transgender)

There is currently no evidence of likely differential impact because of the protected characteristic.

Marriage and civil partnership

There is currently no evidence of likely differential impact because of the protected characteristic.

Pregnancy and maternity

Currently, patients can get free NHS prescriptions if, at the time the prescription is dispensed, they are pregnant or have had a baby in the previous 12 months and have a valid maternity exemption certificate (MatEx). This proposal will potentially increase costs for people with coeliac disease amongst this group of people.

The nutritional status of the unborn baby could be affected if the mother does not adhere to a gluten free diet.

Race

There is currently no evidence of likely differential impact because of the protected characteristic, except where due to literacy issues food labelling may be less well understood if the first language is not English.

Religion or belief

There is currently no evidence of likely differential impact because of the protected characteristic.

Sex

Although coeliac disease is more common in women than men, there is currently no evidence of likely differential impact because of the protected characteristic.

Sexual orientation

There is currently no evidence of likely differential impact because of the protected characteristic.

Carers

There is currently no evidence of likely differential impact because of the protected characteristic.

Other identified groups Detail and consider evidence on groups experiencing disadvantage and barriers to access and outcomes. This can include different socioeconomic groups, geographical area inequality, income, resident status (migrants, asylum seekers).

Currently, patients can get free NHS prescriptions if, at the time the prescription is dispensed, they:

- have a specified medical condition and have a valid medical exemption certificate (MedEx)
- have a continuing physical disability that prevents them from going out without help from another person and have a valid MedEx
- hold a valid war pension exemption certificate and the prescription is for an accepted disability
- Qualify under low income. i.e. hold HC2 changes certificate, receive tax credit, income support, job seekers allowance, universal credit.

People with coeliac disease, amongst these groups of people, may therefore be negatively impacted as a result of this proposal because they will be expected to purchase their gluten free food products.

Mitigating actions:

If there are concerns about safeguarding issues the GP may prescribe.

Engagement and involvement

How have you engaged stakeholders with an interest in protected characteristics in gathering evidence or testing the evidence available?

Herts Valleys CCG and East and North Herts CCG conducted a major public consultation programme called 'Let's Talk' which included this issue, from 6th July – 14th September 2017. Engagement activities included: public meetings in all localities; discussions with local community groups and young people; attendance at community events including Herts Pride and places with high public footfall; promotion via local media; a major social media campaign – primarily via Twitter and Facebook; and sessions in GP practices. In total 2,500 people responded to the survey and thousands more have had access to the consultation information as a whole.

Summary of respondents:

- 68% were female
- 68% were of working age: 19% in 26-40 years age bracket; 49% 41-65 years.
- 31% have disability or long term condition
- 95% white British (population of Herts is 83% white British)
- 38% stated that they have caring responsibilities

More information on this process, including the questions and comments which emerged from the consultation, is included in the presentation on Consultation Findings included earlier in this report.

How have you engaged stakeholders in testing the guidance or programme proposals?

For each engagement activity, please state who was involved, how and when they were engaged, and the key outputs:

Herts Valleys CCG and East and North Herts CCG conducted a major public consultation programme called 'Let's Talk' which included this issue, from 6th July – 14th September 2017. Engagement activities included: public meetings in all localities; discussions with local community groups and young people; attendance at community events including Herts Pride and places with high public footfall; promotion via local media; a major social media campaign – primarily via Twitter and Facebook; and sessions in GP practices. In total 2,500 people responded to the survey and thousands more have had access to the consultation information as a whole.

Summary of respondents:

- 68% female
- Age: 68% were of working age: 19% in 26-40 age bracket; 49% 41-65.
- 31% have disability or long term condition

- 95% white British (population of Herts is 83% white British)
- 38% stated that they have caring responsibilities

In addition we hosted a two hour meeting to discuss the concerns of the patient advocacy groups in September 2017. Nine representatives of Coeliac UK and other patient advocacy groups attended to represent the coeliac population, CEO of both CCGs, Head of Pharmacy and Medicines Optimisation of both CCGs and Head of Communications for HVCCG all attended to listen to concerns raised.

A document answering specific concerns and queries is available on request.

More information on this process, including the questions and comments which emerged from the consultation, is included in the presentation on Consultation Findings included earlier in this report.

Summary of Analysis

Considering the evidence and engagement activity you listed above, please summarise the impact of your work. Consider whether the evidence shows potential for differential impacts, if so state whether adverse or positive and for which groups and/or individuals. How you will mitigate any negative impacts? How you will include certain protected groups in services or expand their participation in public life?

Impact on all patient groups has been considered and will be mitigated where possible.

Eliminate discrimination, harassment and victimisation

The differential impact may be that for people of low income who receive free prescriptions there is a bigger impact because people paying prescription charges will currently be more likely to purchase products to avoid paying a prescription charge. If approved, this change in guidance locally is intended to apply across the whole county and equally to all who have coeliac disease (unless there is a safeguarding issue)

Advance equality of opportunity

Access will improve as no appointment needed in pharmacies or supermarkets and GP appointments will be released for other patients.

Increased cost to patient may impact on whether they view this as a positive impact.

Promote good relations between groups

This guidance will apply equally to all Hertfordshire residents

Next Steps

Please give an outline of what you are going to do, based on the gaps, challenges and opportunities you have identified in the summary of analysis section. This might include action(s) to eliminate discrimination issues, partnership working with stakeholders and data gaps that need to be addressed through further consultation or research. This is your action plan and should be SMART.

This document will be updated following the decision of the joint CCG committee meeting on 12th October 2017.

How will you share the findings of the Equality analysis? This can include sharing through corporate governance or sharing with, for example, other directorates, partner organisations or the public.

The completed Equality Impact Assessment will be published on both Hertfordshire CCG websites if any changes are made to the commissioning of gluten free.

NHS
Herts Valleys
Clinical Commissioning Group

Updating Gluten Free Foods Guidance – Equality Analysis - Equality Impact Assessment Screening Form

Very occasionally it will be clear that some proposals will not impact on the protected equality groups and health inequalities groups.

Where you can show that there is no impact, positive or negative, on any of the groups please complete this form and include it with any reports/papers used to make a decision on the proposal.

Name of guidance / service	Gluten Free Food on Prescription
What is it that is being proposed?	The CCG proposes removing access to gluten free pasta on prescription for those deemed exceptional to the Herts Valleys CCG Gluten Free Food guidance. This is in line with nationally imposed changes to what is allowable on FP10, under Amendment Regulations 2018 which came into force in December 2018.
What are the intended outcome(s) of the proposal	Gluten free products are no longer routinely available on prescription within Herts Valleys CCG. Currently, where a person is deemed an exception to this guidance, certain gluten free fresh or long-life bread, bread/flour mix or pasta can be prescribed. The outcome of this proposal is that gluten free pasta will no longer be prescribable to those deemed exceptions to the guidance. This is in line with nationally imposed changes to what is allowable on FP10, under Amendment Regulations 2018 which came into force in December 2018.
Explain why you think a full Equality Impact Assessment is not needed	A full Equality Impact Assessment was carried out during the development of the Herts valleys CCG Gluten free Food on Prescription guidance. The proposal is an update to that guidance and is as a result of changes to national regulations on what items can be prescribed on NHS FP10. This change is out of Herts Valleys CCG control. This has been discussed and agreed with the Herts Valleys CCG Equality and Diversity Lead.
On what evidence/information have you based your decision?	In addition to the evidence considered as part of the full Equality Impact Assessment, the following NHS England guidance has been considered: 'Prescribing Gluten-Free Foods in Primary Care: Guidance for CCGs', accessed via https://www.england.nhs.uk/wp-content/uploads/2018/11/prescribing-gluten-free-foods-primary-care-guidance-for-ccgs.pdf
How will you monitor the impact of	This is a nationally imposed change. No monitoring is required.

guidance or service?	
How will you report your findings?	This is a nationally imposed change. There will not be any findings to report.

Having considered the proposal and sufficient evidence to reach a reasonable decision on actual and/or likely current and/or future impact I have decided that a full Equality Impact Assessment is not required.	
Assessors Name and Job title Date	Charlotte Earl, Senior Pharmaceutical Advisor 3rd January 2019

Privacy Impact Assessment – Initial Screening tool

1. Guidance	**PIA Completion Details**		
Title: guidance **for the Commissioning of Gluten-free Foods** **Proposed** **Existing** **Date of Completion: 07/06/17** **Review Date:**	**Names & Titles of staff involved in completing** **Stacey Golding, Lead Pharmaceutical Adviser**		
2. Details of the guidance**. Who is likely to be affected by this** guidance**?**			
Staff **Public** **Patients**			
	Yes	**No**	**Please explain your answers**
Technology **Does the guidance apply new or additional information technologies that have the potential for privacy intrusion?**			

(*Example: use of smartcards*)		☒	
Identity **By adhering to the guidance content does it involve the use or re-use of existing identifiers, intrusive identification or authentication?** **(*Example: digital signatures, presentation of identity documents, biometrics etc.)***		☒	
By adhering to the guidance content is there a risk of denying anonymity and de-identification or converting previously anonymous or de-identified data into identifiable formats?		☒	
Multiple Organisations **Does the guidance affect multiple organisations?** **(*Example: joint working initiatives with other government departments or private sector organisations*)**	☒		**There has also been a recent national consultation on the prescribing of gluten free foods. No patient data will be shared.**

Data **By adhering to the guidance is there likelihood that the data handling processes are changed?** ***(Example: this would include a more intensive processing of data than that which was originally expected)***	☐	☒	**The CCG Pharmacy and Medicines Optimisation Team (PMOT) will be involved in additional monitoring of prescribing data to assess the impact of the** guidance **when implemented (this is identifiable by GP practice but not by patient).**
If Yes to any of the above have the risks been assessed, can they be evidenced, has the guidance content and its implications been understood and approved by the department? ***Ticking 'Yes' to any section will require completion of the full screening tool – for advice contact Head of Governance.**			

Assessments Completed by	
Name:	**Stacey Golding and Sarah Crotty**
Position:	**Lead Pharmaceutical Adviser ENH CCG and Head of Pharmacy & Medicines Optimisation HV CCG**

Date:	**03/10/17**

Assessment by Head of Information.

Head of Information name: David Hodson
Lead for Equality and Diversity: Paul Curry

Assessment by SIRO or Caldicott Guardian.

Name: Sheilagh Reavey
Role: Director of Nursing and Quality (E&N Herts)

Name: Diane Curbishley
Role: Director of Nursing and Quality (HVCCG)

Appendix 2 – Quality Impact Assessment

CCGs covered by the scheme:

HVCCG and E&N Herts CCG

Lead CCG:

HVCCG

Project Lead for scheme: Sarah Crotty

Senior Manager/ Executive Sponsor: Lynn Dalton

Brief description of scheme: It is proposed that gluten free foods will no longer be prescribed in Hertfordshire. Patients will either need to follow a gluten free diet using other products or will need to purchase their specialist products for their condition.

Intended Quality Improvement Outcome/s:

As part of prioritising services offered within the CCG to provide maximum healthcare value with the finances available, consideration is being given to stopping gluten free products on prescription. This would allow for reallocation of funding from areas assessed as being of lower value to services which would provide the greatest possible benefit to the population as a whole.

Methods to be used to monitor quality impact: complaints, GP & patient feedback

	Pos/Neg or N/A	**Risk Score if N**	**Comments** (include reason for identifying impact as positive, negative or neutral)	**Full Assessment Required** **No** (Risk > 8 Stage 2 full assessment required)
Duty of Quality Could the proposal impact positively or negatively on any of the following: a) Compliance with NHS Constitution right to: **i.** Quality of Care and Environment	**N**	**4**	i) Coeliac disease which requires you to have a gluten free diet affects 1% or less of the population. Less than half of these patients used to get gluten free products on prescription in Hertfordshire before the guidance was in place, since the guidance came	**4**

ii. Nationally approved treatments/ drugs **iii.** Respect, consent and confidentiality **iv.** Informed choice and involvement **v.** Complain and redress b) Partnerships c) Safeguarding children or adults			into being gluten free foods on prescription has reduced further. Most patients can follow a diet which does not require them to use products which can be prescribed such as gluten free bread, flour, cakes, pasta, etc. People of low income who choose to purchase gluten free products because they can no longer obtain them on prescription may feel that this has a detrimental effect on their finances and so on their overall quality of life. ii) These products are not supported by a NICE TA, and there was a national consultation started in June 2017– October 2017 consulting on national restrictions which has resulted in products available on prescription being reduced. Our guidance goes further and is similar across Herts. iii), iv), No effects v) We have some very vocal patient groups who have told us they will lodge complaints when we bring in the guidance. The feedback from the 'Let's Talk' consultation on gluten free foods not be available on prescription, with the exception of coeliac patients with learning disabilities or where there are safeguarding concerns were: Agree – 77%	

			Disagree – 23% b) No effects c) If there are significant safeguarding or welfare issues such as for learning disability patients exceptions can be made	
NHS Outcomes Framework Could the proposal impact positively or negatively on the delivery of the five domains (assess all separately): 1. Preventing people from dying prematurely 2. Enhancing quality of life 3. Helping people recover from episodes of ill health or following injury 4. Ensuring people have a positive experience of care 5. Treating and caring for people in a safe environment and protecting them from avoidable harm	**n/a**		1) No effect	
	2		2) No effect as most people can follow a diet which does not require them to use products which can be prescribed such as gluten free bread, flour, cakes, pasta, etc. People of low income who choose to purchase gluten free products because they can no longer obtain them on prescription may feel that this has a detrimental effect on their finances and so on their overall quality of life.	**(2+4)** **Total: 6**
	n/a		3) No effect	
	n/a		4) No effect	
	n/a		5) No effect	
Access Could the proposal impact positively or negatively on any of the following: a) Patient Choice b) Access c) Integration			**a), b), c) no effect**	

Name of person completing assessment: Sarah Crotty

Herts Valleys Clinical Commissioning Group

Position: Head of Pharmacy & Medicines Optimisation

Signature: *Sarah Crotty* Date of assessment: 4/1/19

Reviewed by: Lynn Dalton

Position: Director of PC and PMOT



Signature: Date of review: 4/1/19

Proposed frequency of review: Six monthly/ Quarterly/ Monthly/ Other please specify:_____

(minimum monitoring is six monthly (scores 6 or below), every 4 months (scores 8-9), quarterly (scores 10- 12) and monthly (15-20), weekly or more frequent (score 25) Use boxes below to record outcome of reviews

Date of next review: July 2019

Signed off by: Clare Molloy

Position: Deputy Director of Nursing and Quality



Signature:
Date of review: 7/1/19

Requires review at Quality Committee: N

Date considered at Quality Committee:

Logged on spreadsheet: Y/N Date:

Post Implementation Review

(use the template below to record outcomes of reviews- if more than one is required cut and paste the box below)

Have the anticipated quality impacts been realised? Y

Comments: Funding has been released from what would have been spent on gluten free products which has been reallocated to areas of higher priority.

Have there been any unanticipated negative impacts? N

Comments:

Are any additional mitigating actions required? N

Comments:

Herts Valleys
Clinical Commissioning Group

Do any amendments need to be made to the scheme? Y

Comments: The guidance has been reviewed against national guidance and no changes to guidance principles are required. However, the guidance will be updated to reflect additional national restrictions on gluten free product supply via FP10 prescription which came into force in December 2018

Reviewed by: Sarah Crotty

Position: Head of Pharmacy & Medicines Optimisation

Signature: *Sarah Crotty* Date of review: 4/1/19