

Meeting of the Board of NHS Cheshire and Merseyside

28 November 2024

Proposal regarding ICB funded Gluten Free Prescribing across Cheshire and Merseyside

Agenda Item No: ICB/11/24/17

Responsible Director: Prof. Rowan Pritchard-Jones, Medical Director



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Proposal regarding ICB funded Gluten Free Prescribing across Cheshire and Merseyside

1. Purpose of the Report

- 1.1 The purpose of the paper is to seek approval from the Board of NHS Cheshire Merseyside ICB to progress with the commencement of a period of public consultation, regarding ICB funded gluten free (GF) prescribing.
- 1.2 The approval will enable the commencement of a six-week consultation involving patients, public, staff and other key stakeholders, starting January 2025.

2. Executive Summary

- 2.1 Currently within NHS Cheshire and Merseyside there are differences in the prescribing of gluten free products for patients due to previous arrangements of the individual predecessor Clinical commissioning Group (CCG) organisations. As the ICB has commissioning responsibilities for all of Cheshire and Merseyside patients, work has been undertaken to rectify this position and recommend a harmonised approach to prescribing.
- 2.2 Across the 9 Places in Cheshire and Merseyside, there are GP Practices within 8 Places that currently offer gluten free prescribing in line with the 2018 national Department of Health and Social Care (DHSC) consultation outcome, which was to reduce prescribing to bread and bread mixes only. It is of note that St Helens CCG and NHS Cheshire West CCG opted to withdraw prescribing completely (noting this was prior to the national Department of Health and Social Care (DHSC) consultation as detailed above). For Cheshire West Place, the area that was covered by the former NHS Vale Royal CCG did not opt to withdraw prescribing, and as such there are still parts of Cheshire West where gluten free prescribing can be undertaken (Winsford, Northwich, Middlewich and surrounding area).
- 2.3 In Cheshire and Merseyside, over 13,300 patients have a diagnosis of coeliac disease or other conditions which requires management through a gluten free diet. Most people choose to purchase their gluten free foods at supermarkets or other retailers however 2,314 patients receive their gluten free bread and bread mixes via prescription. It should be noted that of the gluten free prescriptions issued, 99% are exempt from prescription charges, with 73% being due to age (under 16 or 18 if in full time education, or over 60 years old) and over 60% of these being over the age of 60.
- 2.4 Under the ICBs Unwarranted Variation Recovery programme, a number of options were considered in order to address the unwarranted variation. The option to maintain the current arrangements was not considered, due to the



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current unharmonised position, and the need to ensure equity across Cheshire and Merseyside. In order to achieve this, the two main options considered were to either fully prescribe across Cheshire and Merseyside at an estimated additional cost of £130k per year (increase annual spend on the service of c.£655k) or to withdraw prescribing completely, offering an estimated annual saving of £525k. (The full options appraisal can be found in Appendix One of this report).

2.5 Initially the review of the current gluten free prescribing policies was undertaken as part of the Clinical Policy Harmonisation programme which involved a clinical working group who recommended to reinstate prescribing across all of Cheshire and Merseyside which is in line with the DHSC consultation outcome. However, this position was not supported by the ICBs Finance, Investment and Our Resources Committee due to the financial challenges faced by NHS Cheshire and Merseyside.

2.6 In the context of NHS Cheshire and Merseyside needing to consider how and where to allocate the fixed resources allocated by NHS England to best meet the healthcare needs of the population they serve, the Unwarranted Variation programme has proposed that gluten free prescribing is stopped across Cheshire and Merseyside due to the following rationale:

- availability of gluten free foods is much greater than it was when the original policies were implemented, and in the six years since the DHSC consultation. It should also be noted that bread is not classed as an essential food item and people can maintain a healthy diet without bread through choosing naturally gluten free foods
- whilst the cost of gluten free bread is still more expensive than non-gluten free there are other gluten free products (e.g. pasta) which are the same price. In addition, improved food labelling and increased awareness enables people to make informed and healthy choices
- Coeliac UK now say that 40% of ICBs have stripped or reduced prescribing. Our research shows that 32% have stopped completely, 61% prescribe bread and bread mixes and 6% offer to under 18s only
- consideration was given to prescribing to under 18s only, however, Cheshire and Merseyside data shows that over 60% of gluten free prescriptions are for patients 60 years old, and therefore could be seen as discriminatory against the older population
- gluten free prescriptions are in the main received by patients who have exemptions from payment, with the majority of this being due to age (73%). Because age exemption does not take into account financial capacity, it is difficult to evidence the individual financial impact on the impacted patients.
- withdrawing prescribing has already been implemented in St Helens and part of Cheshire West and to date we are not aware of any unforeseen consequences
- ceasing ICB funded gluten free prescribing across Cheshire and Merseyside would enable achievement of a harmonised policy and remove existing unwarranted variation in access to these products based on the rationale set out in this document. In addition, it would harmonise the approach to prescribing other foods for conditions impacted by “standard” products e.g.



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lactose intolerance, as NHS Cheshire and Merseyside does not currently prescribe food alternatives for other food allergies / intolerances

- a number of neighbouring ICBs including Lancashire and South Cumbria and Shropshire, Telford and Wrekin have already stopped prescribing.

2.7 A decision to withdraw gluten free prescribing would require a public consultation, and which will also include engagement and/or consultation with our Local Authority colleagues through 8 of the 9 Local authority Health Overview and Scrutiny committees. Included in this report is the proposed engagement and consultation plan, subject to approval received from the Board (see Appendix Two).

2.8 The feedback from the consultation, together with that of the Local Authority Health Overview and Scrutiny Committees will inform the final proposal that will come to Board in 2025 for consideration and decision.

3. Ask of the Board and Recommendations

3.1 **The Board is asked to:**

- **approve** the commencement of a consultation exercise with the public and stakeholders regarding the proposed option to withdraw ICB funded gluten free prescribing across all of Cheshire and Merseyside.

4. Reasons for Recommendations

4.1 A decision by the Board to withdraw ICB funded gluten free prescribing needs to be informed with evidence including the outcome and outputs of a consultation exercise with the public and key stakeholders. It is a legal requirement and duty on the ICB to engage and consult with the public as well as local Health Overview and Scrutiny arrangements.

5. Background

5.1 Currently NHS Cheshire and Merseyside has unwarranted variation in the prescribing of gluten free products across all Places. St Helens CCG and Cheshire West CCG opted to withdraw prescribing completely prior to the national Department of Health and Social Care (DHSC) consultation the outcome of which was to reduce prescribing to bread and bread mixes only in 2018. For Cheshire West Place, the area that was covered by the former NHS Vale Royal CCG did not opt to withdraw prescribing, and as such there are still parts of Cheshire West where prescribing can be undertaken (Winsford, Northwich, Middlewich and surrounding area).

5.2 Coeliac disease is an autoimmune condition associated with chronic inflammation of the small intestine, which can lead to malabsorption of nutrients. Population screening studies suggest that in the UK 1 in 100 people are



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affected. The complications of coeliac disease (which may or may not be present at diagnosis) can include osteoporosis, ulcerative jejunitis, malignancy (intestinal lymphoma), functional hyposplenism, vitamin D deficiency and iron deficiency. People with conditions such as type 1 diabetes, autoimmune thyroid disease, Down's syndrome and Turner syndrome are at a higher risk than the general population of having coeliac disease. First-degree relatives of a person with coeliac disease also have an increased likelihood of having coeliac disease.

- 5.3 Management of coeliac disease is a lifelong gluten free diet. Historically, availability of gluten free foods was limited and expensive, so patients obtained these products via prescribing, however, all major supermarkets now commonly stock a wide range of gluten free foods and the price differential is reducing as demand grows. It should be noted that there have been a number of recent national news articles on the higher cost of these “free from” alternatives and the impact of withdrawing prescribing in context of cost-of-living increases.
- 5.4 Initially the former CCGs gluten free prescribing policies were reviewed as part of the Clinical Policy Harmonisation programme, the objective of which was to review existing policies and the latest evidence base to recommend a single set of policies which would enable all patients to have equitable access. Therefore, the option to continue with the current arrangements was discounted. The review of the gluten free prescribing policy involved a clinical working group who recommended to reinstate prescribing across all of Cheshire and Merseyside in line with the DHSC consultation outcome. However, as this would result in additional annual expenditure of c.£130k, this position was not supported by our Finance, Investments and Resources Committee due to the financial challenges faced by NHS Cheshire and Merseyside.
- 5.5 The review was then progressed under the Reducing Unwarranted Variation programme and the non-prescribing option was considered in context of the patient safety risks, and the requirement to support NHS Cheshire and Merseyside to deliver the financial objectives of the Recovery programme.
- 5.6 It is difficult to evidence the impact of stopping gluten free prescriptions for bread and bread mixes and understanding the impact on affected patients. Whilst there are known risks to not adhering to a gluten free diet, which could have long term health impacts and lead to greater demand on wider health services, there is now greater availability of gluten free foods in supermarkets and other retailers (both in store and on-line), improved food labelling and greater awareness of the impact of non-adherence, which all support the patient to make good food choices for a healthy diet.
- 5.7 The options appraisal paper was initially discussed with the Associate Directors of Quality where the proposal was acknowledged and supported for progression. It was subsequently presented to the Recovery Committee on 16 September 2024 and was then considered by the Strategy and Transformation (S&T) committee at the meeting on 19 September 2024. The S&T committee supported the recommendation to present the preferred option, to cease



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prescribing to the Board and that we progress to a public consultation to inform the outcome. It is of note that the options appraisal was also reviewed and considered by the Clinical Effectiveness Group on 2 October 2024 and the group supported progressing consulting of the proposed preferred option to withdraw prescribing across Cheshire and Merseyside.

6. [Link to delivering on the ICB Strategic Objectives and the Cheshire and Merseyside Priorities](#)

Objective One: Tackling Health Inequalities in access, outcomes and experience

- The proposal seeks to remove unwarranted variation in access to prescribing for gluten free bread and bread mixes. It is of note that prescriptions are not available for other food allergies / intolerances, so this will further remove unwarranted variation. GF goods are much more widely available in supermarkets and other retailers both in store and on-line and therefore more accessible to patients. Food labelling has improved so patients are able to identify naturally gluten free foods, and there is greater awareness of the impact of not following a GF diet, so patients are more informed to make healthy diet choices. In addition, it would harmonise the approach to prescribing other foods for conditions impacted by “standard” products e.g. lactose intolerance.

Objective Two: Improving Population Health and Healthcare

- The ICB has a duty to consider how and where to allocate the fixed resources that it receives from NHS England, and this proposal to stop prescribing GF bread and bread mixes will enable the ICB to save an estimated £525k per year which could be allocated to more critical services.

Objective Three: Enhancing Productivity and Value for Money

- The ICB has a duty to consider how and where to allocate the fixed resources that it receives from NHS England, and this proposal to stop prescribing GF bread and bread mixes will enable the ICB to save an estimated £525k per year which will support delivery of the financial recovery plan or allow funds to be reallocated to more critical services.

Objective Four: Helping to support broader social and economic development

- This proposal does not directly contribute to this objective.

7. [Link to achieving the objectives of the Annual Delivery Plan](#)

This proposal is aligned to the annual delivery plan through the Effective Use of Resource element contributing to the delivery of clinical policy harmonisation and supporting the finance efficiency and value programme.



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8. Link to meeting CQC ICS Themes and Quality Statements

Theme One: Quality and Safety

Key to both the clinical policy harmonisation and unwarranted variation programmes is the focus on ensuring all Cheshire and Merseyside residents have equal access to services. In addition, sustainability of services must be considered when making decisions on how to spend limited resource. A QIA has been completed and reviewed by the Associate Directors of Quality who support the proposal to stop prescribing based on re-allocation of this resource to focus on other critical services. (The QIA is available in appendix four).

Theme Two: Integration

The proposal does not directly relate to this theme, however, in relation to the 'safe systems' quality statement, if supported by the Board the next step will be a public consultation which will enable the views of the population to help shape the outcome.

Theme Three: Leadership

If the proposal is supported by the Board, there will be a public consultation exercise through which we will work with wider partners and stakeholders, including providers of NHS services, local authorities, Healthwatch, and voluntary, community, faith and social enterprise (VCFSE) organisations to support us to engage with the right people. We will engage throughout with our Local Authority colleagues through the Health Overview and Scrutiny committees in the impacted Places. This relates to the 'partnerships and communities' quality standard.

9. Risks

- 9.1 It is difficult to evidence the impact of Coeliac patients not being able to access gluten free bread and bread mixes, but there are known risks to not adhering to a gluten free diet which could have long term health impacts and lead to greater demand on wider health services. An example given by Coeliac UK states it costs £195 a year per patient to support gluten free on prescription, but the average cost to the NHS of an osteoporotic hip fracture is £27,000.
- 9.2 Mitigation: A published DHSC Impact Assessment examines the issue of adherence in detail and concludes that adherence to a gluten free diet cannot be isolated to any single cause. Evidence shows that many factors are at play including product labelling, cost and information when eating out and managing social occasions. Adherence requires a range of knowledge and skills to avoid all sources of gluten. Gluten free foods are now much more readily available in supermarkets and other retailers, both in store and on-line, making them more accessible. In addition, there is improved food labelling across all foods and greater awareness of adherence to gluten free diet helping people to make healthy choices. It should be noted that although gluten free bread and bread mixes are still more expensive, the cost of these products has been reducing



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over time and there are other GF foods at comparable prices to standard foods for example 500g of GF pasta being the same price as 500g of standard pasta. It is also worth noting that bread is not an essential food item and there are many naturally occurring GF foods.

- 9.3 There is a reputational risk to the ICB if the proposal to stop prescribing is accepted. Due to the current cost of living, there have been a number of national articles on the increased cost of “free from” foods despite them being much more available. In addition, 99% of the cohort of patients receiving prescriptions have an exemption in that they do not pay for prescriptions so could be seen that we are disadvantaging our most vulnerable population.
- 9.4 Mitigation: A public consultation would be held in those Places who currently prescribe, the outcome of which will inform the final decision. It should be noted that the ICB does not prescribe food products for other conditions that are associated with or affected by types of food.

10. Finance

- 10.1 If the proposal is supported by the Board and implemented following a public consultation exercise, this would offer the ICB an estimated annual saving of £525k and a cost avoidance of a further £130k (the estimated cost of harmonising prescribing across all Places).
- 10.2 The public consultation exercise would be led by NHS Cheshire and Merseyside’s in-house communications and engagement team; however, it is anticipated that up to £12,000 one-off enabling funding will be required to support delivery. This would include analysis of consultation findings and production of a report to inform the final decision, and funding for additional formats, including easy read versions and other languages. It is standard practice for public consultation reports to be produced by an external organisation.

11. Communication and Engagement

- 11.1 A supporting comms and engagement plan is available in appendix two.

12. Equality, Diversity and Inclusion

- 12.1 An equality, diversity and inclusion assessment (EIA) was undertaken and can be viewed in appendix three.

13. Climate Change / Sustainability

- 13.1 This proposal does not directly relate the ICB green plan or net zero obligations.

14. Next Steps and Responsible Person to take forward

- 14.1 If the recommendation to progress consulting on our proposal for ICB funded gluten free prescribing, a public consultation exercise will be held, with proposed start date of January 14th 2025 continuing for six-weeks until Tuesday February 2025.
- 14.2 Engagement will commence with Local Authority Health Overview and Scrutiny committees to determine how best to engage and/or consult with them.
- 14.3 Feedback on the consultation will inform the final recommendation put to the which will be presented to a future Board meeting for Board decision.
- 14.4 The work will be taken forward by the Reducing Unwarranted Variation Programme Team under the direction of Anthony Leo as Senior Responsible Officer, Professor Rowan Pritchard-Jones as Clinical Lead and Natalia Armes as Programme Director.

15. Officer contact details for more information

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16. Appendices

- Appendix One:** Gluten Free Prescribing Options Appraisal document
- Appendix Two:** Communications and Engagement Plan
- Appendix Three:** Equality, Diversity and Inclusion Impact Assessment
- Appendix Four:** Quality Impact Assessment



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**Options Appraisal ICB funded Gluten
Free products Prescribing across
Cheshire and Merseyside**



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Glossary

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

1 Executive Summary

Currently NHS Cheshire and Merseyside has unwarranted variation in the prescribing of gluten free products across all Places. St Helens CCG and Cheshire West CCG opted to withdraw prescribing completely (to note the footprint previously under Vale Royal CCG within Cheshire West Place still undertake some prescribing) prior to the national Department of Health and Social Care (DHSC) consultation the outcome of which was to reduce prescribing to bread and bread mixes only in 2018.

In Cheshire and Merseyside, over 13,300 patients have a diagnosis of coeliac disease or other conditions which requires management through a gluten free diet. Most people choose to purchase their gluten free foods at supermarkets or other retailers however 2,314 patients receive their gluten free foods via prescription. It should be noted that of the prescriptions issued, 99% are exempt from prescription charges, with 73% being due to age (under 16 or 18 if in full time education, or over 60 years old) and over 60% of these being over the age of 60.

Under the Unwarranted Variation Recovery programme, a number of options were considered in order to address the unwarranted variation, but the 2 main options were to either fully prescribe across Cheshire and Merseyside at an estimated additional cost of £130k per year (increase annual spend on the service of c.£655k) or to withdraw prescribing completely offering an estimated annual saving of £525k.

Initially the review of the current gluten free prescribing policies was carried out under the Clinical Policy Harmonisation programme and involved a clinical working group who recommended reinstating prescribing across all of Cheshire and Merseyside which is in line with the DHSC consultation outcome. However, this position was not supported by our Finance, Investments and Resources Committee due to the financial challenges faced by NHS Cheshire and Merseyside.

In the context of the financial challenge facing NHS Cheshire and Merseyside, the Unwarranted Variation programme has reviewed all options and are proposing that gluten free prescribing is stopped due to the following rationale:

- Availability of gluten free foods is much greater than it was when the original policies were implemented, and in the six years since the DHSC consultation. It should also be noted that bread is not classed as an essential food item and people can maintain a healthy diet without bread through choosing naturally gluten free foods.
- Whilst the cost of gluten free bread is still more expensive than non-gluten free there are other products (e.g. pasta) which are the same price. In addition, improved food labelling and increased awareness enables people to make informed and healthy choices.
- Coeliac UK now say that 40% of ICBs have stopped or reduced prescribing, our research shows that 32% have stopped completely, 61% prescribe bread and bread mixes and 6% offering to under 18s only.
- Consideration was given to prescribing to under 18s only, however, C&M data shows that over 60% of the population receiving prescriptions are over 60 years and therefore could be seen as discriminatory against the older population.
- Gluten free products are in the main received by patients who have exemptions from payment, with the majority of this being due to age (73%) and because exemption does not take into account financial capacity, it is difficult to evidence the individual financial impact on the impacted patients.
- Withdrawing prescribing has already been implemented in St Helens and part of Cheshire West and to date we are not aware of any unforeseen consequences.
- NHS Cheshire and Merseyside do not currently prescribe food alternatives for other food allergy / intolerances e.g. lactose intolerance.
- A number of our ICB neighbours including Lancashire and South Cumbria and Shropshire, Telford and Wrekin have already stopped prescribing.

A decision to withdraw gluten free prescribing would require a public consultation in 8 of the 9 Places including engagement with our Local Authority colleagues through Oversight and Scrutiny committees.

The options appraisal paper was initially discussed with the Associate Directors of Quality where the proposal was acknowledged and supported for progression. It was subsequently presented to the Recovery Committee on 16th September and was then considered by the Strategy and Transformation (S&T) committee at the meeting on 19th September. The S&T committee supported the recommendation to present the preferred option, to cease prescribing to the Board for approval to progress to a public consultation to inform the final decision.

It is of note that the options appraisal was also reviewed and considered by the Clinical Effectiveness Group on 2nd October and the group supported progress of the proposed option to withdraw prescribing across Cheshire and Merseyside.

The Board is asked to approve the recommendation to progress a proposal for a non-prescribing option for gluten free bread and bread mixes in order to commence a public consultation starting in January 2025. The feedback from this exercise, together with that of our Oversight and Scrutiny Committees will inform the decision whether to continue with this recommended option. In addition, the Board is asked to receive the feedback from this exercise at the first available board meeting.

2 Background

Currently NHS Cheshire and Merseyside has unwarranted variation in the prescribing of gluten free products across all Places. St Helens CCG and Cheshire West CCG opted to withdraw prescribing completely prior to the national Department of Health and Social Care (DHSC) consultation the outcome of which was to reduce prescribing to bread and bread mixes only in 2018. Further information about this consultation and the revised regulation subsequently put in place is available on the NHS England website ([NHS England » Prescribing Gluten-Free foods in Primary Care: Guidance for Clinical Commissioning Groups – frequently asked questions](#)). For Cheshire West Place, the area that was covered by the former Vale Royal CCG did not opt to withdraw prescribing, and as such there are still part of Cheshire West were prescribing can be undertaken (Winsford, Northwich, Middlewich and surrounding area).

Coeliac disease is an autoimmune condition associated with chronic inflammation of the small intestine, which can lead to malabsorption of nutrients. Population screening studies suggest that in the UK 1 in 100 people are affected. The complications of coeliac disease (which may or may not be present at diagnosis) can include osteoporosis, ulcerative jejunitis, malignancy (intestinal lymphoma), functional hyposplenism, vitamin D deficiency and iron deficiency. People with conditions such as type 1 diabetes, autoimmune thyroid disease, Down's syndrome and Turner syndrome are at a higher risk than the general population of having coeliac disease. First-degree relatives of a person with coeliac disease also have an increased likelihood of having coeliac disease.

Management of coeliac disease is a lifelong GF diet. Historically, availability of GF foods was limited and expensive, so patients obtained these products via prescribing, however, all major supermarkets now commonly stock a wide range of GF foods and the price differential is reducing as demand grows. It should be noted that there have been a number of recent national news articles on the higher cost of these "free from" alternatives and the impact of withdrawing prescribing in context of cost-of-living increases.

Initially the former CCGs gluten free prescribing policies were reviewed as part of the Clinical Policy Harmonisation programme and involved a clinical working group who recommended to reinstate prescribing across all of Cheshire and Merseyside in line with the DHSC consultation outcome.

However, as this would result in additional annual expenditure of C.£130k, this position was not supported by our Finance, Investments and Resources Committee due to the financial challenges faced by NHS Cheshire and Merseyside

The review was then progressed under the Unwarranted Variation programme and the non-prescribing option was considered in context of the patient safety risks, and the requirement to support NHS Cheshire and Merseyside to deliver the financial objectives of the Recovery Programme.

It is difficult to evidence the impact of stopping GF prescriptions and understanding whether the impacted patients would continue to follow a GF diet. Whilst there are known risks to not adhering to a GF diet, which could have long term health impacts and lead to greater demand on wider health services, there is greater availability of GF foods in supermarkets and other retailers, improved food labelling and greater awareness of the impact of non-adherence, which all support the patient to make good food choices for a healthy diet.

The options appraisal paper was initially discussed with the Associate Directors of Quality where the proposal was acknowledged and supported. It was subsequently presented to the Recovery Committee on 16th September and was then considered by the Strategy and Transformation (S&T) committee at the meeting on 19th September. The S&T committee supported the recommendation to present the preferred option, to cease prescribing to the Board and that we progress to a public consultation to inform the outcome. In addition, the Clinical Effectiveness Group also supported progression of the proposed option on 2nd October.

3 Approach

The gluten free prescribing policy was initially reviewed under the Clinical Policy Harmonisation Programme (CPH) the objective of which was to review existing policies and the latest evidence base to recommend a single set of policies which would enable all patients to have equitable access. The review of the gluten free prescribing policy focused on the published evidence base DH&SC and Coeliac UK recommendations with input from clinicians, dieticians and pharmacists and was led by the CPH Steering Group which includes commissioners, GP, Pharmacist and public health leads. An options appraisal was carried out to consider a number of options to harmonise the prescribing position and an EIA and QIA were developed to consider all options. Therefore, the option to continue with the current arrangements was discounted.

The CPH programme recommended that the harmonised policy be to implement gluten free prescribing in accordance with DHSC guideline, however, this comes at an additional annual cost of C.£130k and this was not able to be supported by the Finance, Investment and Resources Committee at the time. It is of note that this work was placed on hold, due to the financial pressures and pre-election activity so it was brought into the scope of the Reducing Unwarranted Variation Recovery Programme (noting that 3 members are consistent with the previous Clinical Policy Steering Group) and review has also been completed by the Deputy Medical Director and Clinical Lead for Reducing Unwarranted Variation (RUV) Programme.

In the context of the ICB financial recovery plan, the RUV programme carried out a further review which considered Cheshire and Merseyside data, prices and availability of GF foods in supermarkets and other retailers, both instore and on-line, improvements in food labelling and increased information via websites on how to maintain a GF diet. Following discussions on these findings with Place Clinical Directors and Associate Directors of Quality, the Reducing Unwarranted Variation Steering group **is recommending as a financial decision, prescribing is stopped across Cheshire and Merseyside** and this view is supported by the Deputy Medical Director and Programme Clinical Lead.

The group recognised that this goes against the latest published guidance, however, it should be noted that this is now 6 years old, and this is not a medicine or prescription for an essential food item (as it is for bread or bread mixes only). In addition, the group noted that this is a similar stance as taken with other food allergies / intolerances and dietary requirements where we do not offer alternative food items by prescription and increasing affordable gluten free products are available at supermarkets. This

recommendation would result in a financial saving of circa. £525k and avoid additional expenditure of £130k.

3.1 Current Cheshire and Merseyside Activity and Spend on Gluten Free Prescribing

Across Cheshire and Merseyside, 8 Places still have a Policy that includes GF prescribing at an annual cost of circa £525k for the year 2023/2024. Prior to the establishment of the ICB, two of the former CCGs (St Helens and West Cheshire) withdrew GF prescribing as a cost cutting policy, although it is of note that GP practices in the former Vale Royal CCG footprint still prescribe as shown within the table below.

Cheshire and Merseyside - Gluten Free Prescribing 2023/24

Row Labels	Sum of Items	Sum of Actual Cost	Weighted Pop	per 1,000 Wtd Pop.	
				Items	Actual Cost
Sefton	3816	£87,559	310666	12.28	£281.84
CHESHIRE EAST	4909	£97,731	429865	11.42	£227.35
Knowsley	2156	£46,220	196251	10.99	£235.52
Halton	1551	£32,413	149417	10.38	£216.93
Wirral	3724	£77,017	385940	9.65	£199.56
Liverpool	5953	£122,669	646320	9.21	£189.80
Warrington	1953	£41,160	232237	8.41	£177.23
CHESHIRE WEST & CHESTER	939	£19,396	410116	2.29	£47.29
St Helens	20	£413	231122	0.09	£1.79
Grand Total	25021	£524,579	2991933	8.36	£175.33

Gluten Free Prescribing Exemption in Cheshire and Merseyside

In Cheshire and Merseyside over 13,300 patients have a diagnosis of coeliac disease, with only 17.4% (2,314) receiving prescription gluten free food.

The table below details the breakdown of GF prescriptions across Cheshire and Merseyside and shows that 99% of prescriptions issued are currently exempt from prescription charges.

Row Labels	Chargeable at Current Rate		Exempt	
	Number of Items	Proportion	Number of Iter	Proportion
Cheshire East	21	1.03%	2020	98.97%
Cheshire West	11	2.72%	393	97.28%
Halton	6	0.93%	637	99.07%
Knowsley	5	0.57%	869	99.43%
Liverpool	24	0.96%	2465	99.04%
Sefton	5	0.32%	1556	99.68%
St Helens		0.00%	10	100.00%
Warrington	6	0.76%	785	99.24%
Wirral	14	0.93%	1488	99.07%
Cheshire and Merseyside	92	0.89%	10223	99.11%

Of these exemptions, 73% is due to age (under 16 or 18 if in full time education, or over 60 years old), with the majority being over the age of 60.

According to Coeliac UK, most people are diagnosed from 50 years old and coeliac disease is most common in people aged between 50-69 years old.

Row Labels	Exempt	
	Number of Items	Proportion
Aged 60 Or Over	6253	61.17%
No Declaration/Declaration Not Specific	1950	19.07%
Under 16 / Aged 60 Or Over	898	8.78%
Pre-Payment Certificate	315	3.08%
Aged 16-18 And In Full Time Education	311	3.04%
Medical Exemption	287	2.81%
Income Support	87	0.85%
Universal Credit	64	0.63%
HC2 Charges	19	0.19%
NHS Tax Credit Exemption Certificate	19	0.19%
Maternity Exemption	15	0.15%
Income Based Job-seekers Allowance	3	0.03%
HRT Pre-payment Certificate	1	0.01%
Pension Guarantee Credit	1	0.01%
Unassigned		0.00%

3.2 Current Prescribing Approaches across England (where available)

Coeliac UK state that 40% of ICBs have stopped or reduced prescribing. Where the information was published, our research shows that 32% have stopped completely with 61% prescribing bread and bread mixes, 6% prescribing to under 18s only and 6% prescribe bread only. (see appendix E).

The table below shows the policy stance of local ICBs:

Prescribe bread & bread mixes	Do not prescribe – all ages
<ul style="list-style-type: none"> Greater Manchester – all ages Staffordshire – for those under age of 18 only 	<ul style="list-style-type: none"> Lancashire and South Cumbria Shropshire, Telford and Wrekin

3.3 Guiding principles:

- To reduce unwarranted variation and harmonise access to services across Cheshire and Merseyside.
- Use the latest evidence base to develop harmonised policies
- Consider sustainability of Cheshire and Merseyside ICB in context of financial requirements

3.4 Strategic Context

The main objectives identified are:

Objective 1	
Objective	Tackling health inequality, improving outcomes and access to services
Current Arrangement	<p>7* of 9 Places currently offer gluten free prescribing in line with the national Department of Health and Social Care (DHSC) consultation the outcome of which was to reduce prescribing to bread and bread mixes only in 2018. It is of note that for the remaining 2 Places, St Helens CCG and Cheshire West CCG opted to withdraw prescribing completely (noting this was prior to the national Department of Health and Social Care (DHSC) consultation as detailed above).</p> <p>*For Cheshire West Place, the area that was covered by the former Vale Royal CCG did not opt to withdraw prescribing, and as such there are still part of Cheshire West were prescribing can be undertaken (Winsford, Northwich, Middlewich and surrounding area).</p> <p>In addition, there are other patients who are diagnosed with food related allergies / intolerance conditions who do not receive prescriptions to</p>

Objective 1	
	manage their diet and therefore could be argued that those patients are disadvantaged by a prescribing option.
Gap/Business Needs	In order to harmonise the position across C&M, there are 2 options, one to implement prescribing across all 9 Places at a potential additional cost of £130k per year; a total estimated cost of £655k per year or to withdraw prescribing across all 9 places at a potential saving of £525k per year.
Objective 2	
Objective	Enhancing quality, productivity and value for money
Current Arrangement	<p>7* of 9 Places currently offer gluten free prescribing in line with the national Department of Health and Social Care (DHSC) consultation the outcome of which was to reduce prescribing to bread and bread mixes only in 2018. It is of note that for the remaining 2 Places, St Helens CCG and Cheshire West CCG opted to withdraw prescribing completely (noting this was prior to the national Department of Health and Social Care (DHSC) consultation as detailed above).</p> <p>*For Cheshire West Place, the area that was covered by the former Vale Royal CCG did not opt to withdraw prescribing, and as such there are still part of Cheshire West were prescribing can be undertaken (Winsford, Northwich, Middlewich and surrounding area).</p> <p>In addition, there are other patients who are diagnosed with food related allergies / intolerance conditions who do not receive prescriptions to manage their diet and therefore could be argued that those patients are disadvantaged by a prescribing option.</p> <p>There is a risk to patient safety if patients do not follow a GF diet (quality) and potential impact on wider services in the future.</p>
Gap/Business Needs	In order to harmonise the position across C&M, there are 2 options, one to implement prescribing across all 9 Places at a potential additional cost of £130k per year; a total estimated cost of £655k per year or to withdraw prescribing across all 9 places at a potential saving of £525k per year.

4 Options and considerations

No	Description	Outcome	EIA Feedback*	QIA Feedback*	Financial Impact
1	Do nothing -discounted option	Inequity of prescribing for patients across C&M	No EIA completed	No change to current situation, but unwarranted variation across C&M	Current annual spend of circa £525,000 will be maintained
2	NHS C&M adopt prescribing to national guidelines across all Places	Harmonised C&M policy in line with evidence base. Public involvement exercise could be minimal as there has already been a full consultation by DHSC.	In line with DHSC EIA guidance following extensive public consultation and EIA completion (see appendix F). If not prescribed will be contrary to national published guidance, however, this EIA is now 8 years old. Minimal equality impact identified. (see appendix A)	Equity across C&M and improves access to patients in the Places who do not currently receive prescribed gluten free goods. Overall Risk rating: 1 Green – Low risk (see appendix B)	Estimated increase in spend of £130,000. Estimated annual spend £655,000
3	NHS C&M to withdraw prescribing across all Places	Harmonised C&M policy contrary to published guidance however, this is now 6 years old. Public consultation exercise would be required in 8 Places	A number of groups of patients could be at risk of dietary neglect as clear links were identified between: - age (those aged under 16, those aged 16, 17 and 18 in full time education, and those aged 60 or over are eligible for prescription exemptions) - Gender (reported cases of coeliac disease are two to three times higher in women than men), -pregnancy and maternity (e.g. Poorly controlled coeliac disease in pregnancy can increase the risk of developing pregnancy-related complications) (see appendix C)	Withdrawal of prescribing would impact those patients who receive free prescriptions who are likely to be vulnerable due to low income, holding medical certificates which implies wider health needs and age. There is a risk in this current economic climate that people on low income would consume non-GF bread and bread mixes which could have longer term health impacts and therefore increase health inequalities. (see appendix D)	Most current spend would cease leading to an estimated saving of £525,000 with further estimated cost avoidance of £130k Estimated annual spend £0

No	Description	Outcome	EIA Feedback*	QIA Feedback*	Financial Impact
			- Families on low income (due to eligibility for exemptions from prescription charges)	Overall Risk rating: 4 Amber – moderate	
4	Prescribe to under 18s only – discounted option	Harmonised policy but only for young people, therefore inequity of access for patients across C&M. Public consultation would be required in all 9 Places.	<p>This option is against published guidelines (& this would benefit less than 15% of the C&M population receiving GF prescriptions). A number of groups of patients could be at risk of dietary neglect as clear links were identified between:</p> <ul style="list-style-type: none"> - age and in particular those aged 60 or over are eligible for prescription exemptions - Children and young people are not financially independent so this option would support them to adhere to a GF diet - Gender (reported cases of coeliac disease are two to three times higher in women than men), -pregnancy and maternity (e.g. Poorly controlled coeliac disease in pregnancy can increase the risk of developing pregnancy-related complications) - Families on low income (due to eligibility for exemptions from prescription charges) 	<p>Withdrawal of prescribing would impact those patients who receive free prescriptions who are likely to be vulnerable due to low income, holding medical certificates which implies wider health needs and age. There is a risk in this current economic climate that people on low income would consume non-GF bread and bread mixes which could have longer term health impacts and therefore increase health inequalities.</p> <p>Whilst this option would support younger people, they make up less than 15% of the C&M population receiving GF prescriptions.</p>	Based on 10% of current spend estimated costs would be £50,000 - £60,000 per annum. This results in a saving of £465,000 - £475,000

4.1 Risks, Constraints & Dependencies

The following risks, constraints and dependencies have been highlighted as part of the development of the case for change.

Risks

The following risks have been identified with the achievement of the programme outcomes:

Risk	Mitigating actions
<p>It is difficult to evidence the impact of Coeliac patients not being able to access Gluten Free (GF) bread and bread mixes, but there are known risks to not adhering to a GF diet which could have long term health impacts and lead to greater demand on wider health services. An example given by Coeliac UK states it costs £195 a year per patient to support GF on prescription, but the average cost to the NHS of an osteoporotic hip fracture is £27,000.</p>	<p>A published DHSC Impact Assessment examines the issue of adherence in detail and concludes that adherence to a GF diet cannot be isolated to any single cause. Evidence shows that many factors are at play including product labelling, cost and information when eating out and managing social occasions. Adherence requires a range of knowledge and skills to avoid all sources of gluten. Gluten free foods are now much more readily available in supermarkets, with clear gluten free labelling. It should be noted that although GF bread and bread mixes are still more expensive the cost of these products has been reducing over time and there are other GF foods at comparable prices to standard foods for example 500g of GF pasta being the same price as 500g of standard pasta. It is also worth noting that bread is not an essential food item and there are many naturally free GF foods e.g. potatoes, rice.</p> <p>If the option to stop prescribing was accepted, signposting on how to adhere to a gluten free diet would be made available on the ICB website and GPs would continue to monitor these patients as usual.</p> <p>Also engagement with supermarkets in Cheshire and Merseyside would be undertaken to advise of the change in prescribing with a request for them to manage their stock levels accordingly.</p>
Risk	Mitigating actions
<p>There is a reputational risk to the ICB if the option to withdraw prescribing is accepted. Due to the current cost of living, there have been a number of national articles on the increased cost of “free from” foods despite them being much more available. In addition, 99% of the cohort of patients receiving prescriptions have an exemption in that they do not pay for prescriptions so</p>	<p>The ICB does not prescribe for other conditions that are associated with, or affected by the types of food they eat, so this would result in a fairer approach for these patients.</p> <p>A public consultation exercise would be held in those Places who currently prescribe in line with the approach in St Helens and the relevant area of Cheshire West.</p>

<p>could be seen that we are targeting our most vulnerable population.</p>	
<p>If the option to re-instate prescribing is accepted, there is a financial risk to the ICB in that an additional £130k per year would be required to support this, meaning an estimated annual spend of £655k.</p> <p>This may result in other critical funded services not being funded as a consequence of the further cost pressure.</p>	<p>Place based Medicines Management teams would review prescribing quantities to ensure they are in line with Coeliac UK guidance. This may mitigate some of the cost.</p> <p>Noting that this option is not the recommended option of the Reducing Unwarranted Variation Steering Group.</p>

Constraints

- The review is being undertaken in context of the recovery programmes.
- Due to the significance of the change, a public consultation exercise would be required if any option to withdraw prescribing was accepted. In addition, it would be necessary to engage and consult with the Oversight and Scrutiny Committees in all affected Places. A Joint OSC meeting would need to be formed, composed of the Local Authorities where the population would be impacted. The availability and timing of these meeting would be largely dictated by the Local Authorities. This would impact the timing of benefits delivery.
- Engagement/communication would also be required with local MPs.
- Consideration is needed regarding any delays to benefits delivery caused by the potential for ‘call in’ to the SoS for Health & Care of any proposed service change – members of the public or organisations can write to the Secretary of State at any stage of the process.

Dependencies

- NHS Cheshire and Merseyside’s communications and engagement team is currently focused on a number of pieces of public involvement work. Any public involvement requirements around gluten-free prescribing will need to be considered alongside existing work plans.
- Public involvement activity has resource implications. It is standard practice to commission independent analysis and reporting of feedback from public consultation, aside from any additional requirements around delivery of consultation activity. There is a need to scope out the requirements and identify the necessary budget.

5 Options Appraisal and Financial Case

For completeness a range of options have been considered as part of the case for change, a brief description of full range of options is below:

Option 1: Do nothing – 8 of 9 Places prescribe GF products, St Helens and part of Cheshire West do not prescribe (Option discounted)

Pros	Cons
<ul style="list-style-type: none"> The financial position of the ICB does not change. 	<ul style="list-style-type: none"> There is unwarranted variation across Cheshire and Merseyside in unequal access to GF bread and bread mixes for our patients. There is an increased risk of challenge by Equalities and Human Rights commission re inequality in service access. Financial impact remains at circa £525k per annum.

Option 2: Implement Prescribing of bread and bread mixes across whole of Cheshire and Merseyside

Pros	Cons
<ul style="list-style-type: none"> Harmonised access to GF bread and bread mixes across C&M In line with evidence base Supported by Quality and EDI Teams and Clinicians Review of the quantities prescribed in each Place could mitigate the additional cost 	<ul style="list-style-type: none"> Additional estimated annual cost of £130k making a total of estimated annual cost £655k per annum This may impact the ability to support other areas of need due to financial constraints across the Integrated Care System. There are other patients who suffer from other food allergies or intolerances who do not receive prescribed food goods, this option could be seen as increasing inequity for these patients.

Proposed next steps and estimated timeframe for Option 2:

- 1) Recovery Committee (September 16th) and Strategy & Transformation Committee (STC) (19th September) supported recommendation to withdraw prescribing
- 2) The recommendation from STC to be considered and decision to be ratified by Board – 28th November 24
- 3) Public Involvement exercise in St Helens and Cheshire (West Vale Royal GP Practices) (working assumption is this would be a communications exercise)
- 4) Harmonised policy to be launched across all Places – no change for 8 of 9 – December 24

Option 3: Withdraw Prescribing across whole of Cheshire and Merseyside

Pros	Cons
<ul style="list-style-type: none"> • Harmonised access to GF products across C&M • Financial benefit to the ICB of £525k per annum • Increased fairness in prescribing policies as NHS does not provide food on prescription for other groups of patients who conditions are associated with, or affected by, the type of food they eat. 	<ul style="list-style-type: none"> • Contrary to the latest published guidance, however, this is now 8 years old and the prices of GF goods have been reducing, therefore would be purely financial rationale • Concerns identified through the EIA and QIA process particularly around the impact on vulnerable patients (particularly age) and for those patients on low income the risk of increasing health inequalities. • Consultation required in 8 places. Time delay and potential cost to develop outcomes report. • Risk of negative publicity for ICB particularly in local press. • Increased risk of challenge by EHRC (as per above) • Increased risk of judicial review raised by individuals/organisations

Proposed next steps and estimated timeframe for Option 3:

- 1) Recovery Committee (September 16th and Strategy & Transformation Committee (19th September) support recommendation
- 2) Public consultation plan and materials to be developed.
- 3) The preferred option (subject to public consultation), and public consultation plan, to be approved by Board – 28th November 24
- 4) Public consultation exercise 8 weeks (subject to further discussion around timings and resources) – January 25 to February 25
- 5) Feedback and analysis report on consultation completed (approx. 4 weeks required) – March 25
- 6) Engagement with OSC on feedback from consultation exercise – to be confirmed
- 7) Feedback on consultation exercise presented to Board. Board asked to decide on whether to proceed with no GF prescribing approach – to be confirmed
- 8) Feedback on consultation exercise and Board decision presented to OSC - TBC
- 9) Subject to outcomes of public consultation and final decision-making, policy launch & benefits realisation start – to be confirmed

Option 4: Prescribe to under 18s only (Option discounted)

Pros	Cons
<ul style="list-style-type: none"> • Harmonised approach to prescribing of GF bread and bread mixes across C&M • Financial benefit to the ICB of £465,000 - £475,000 per annum • Would support the younger coeliac patients to follow a correct diet until adulthood. 	<ul style="list-style-type: none"> • Contrary to evidence base • Concerns identified through the EIA and QIA process around the impact on vulnerable patients particularly age (as over 60% of issued GF prescriptions are due to patients being aged 60+) and for those adult patients on low income as there is a risk of increasing health inequalities • Would require public engagement in all 9 Places • Risk of negative publicity for ICB particularly in local press. • This option does not provide a service for the majority of patients who are currently receiving GF prescriptions (15% under 19yo) • Increased risk of challenge by EHRC (as per above) • Increased risk of judicial review raised by individuals/organisations

5.1 Financial Case: Following the initial options assessment, Options 1 and 4 have been discounted.

Options	Description (*Committed costs)	Non-recurrent Year 1	Non-recurrent Year 2	Recurrent costs (Annual)	Comments
Option 1: Do nothing – 8 of 9 Places prescribe GF products, St Helens and part of Cheshire West do not	£525,000	£525,000	£530,000	£538,000 (yr 3)	Based on ONS population growth projection
Option 2: Implement Prescribing across whole of Cheshire and Merseyside	£650,000	£650,000	£661,700	£672,287 (yr 3)	Based on ONS population growth projection, however, could increase if cost of products or activity increases. Place prescribing Teams would also review prescribing quantities to ensure all in line with guidance.
Option 3: Withdraw Prescribing across whole of Cheshire and Merseyside	-£525,000	-£525,000	-£525,000	-£525,000	Provides a consistent approach to prescribing for food intolerances. Whilst this does not adhere to published guidance, this is now 6 years old. It is of note that the £525k is a cash releasing saving with a further cost avoidance of £130k.
Option 4: Prescribe to under 18s only	-£465,000 - £475,000	-£465,000 - £475,000	-£465,000 - £475,000	-£465,000 - £475,000	Not in line with published guidance and does not reflect the need of C&M demographics

6 Recommendation

In the context of the Recovery Programme and following further review and the formation of this options appraisal, the Reducing Unwarranted Variation Steering Group recommend the progression to public consultation of option 3, to withdraw prescribing of bread and bread mixes. This recommendation has also been discussed by the Deputy Medical Director and Associate Directors of Quality, and also with the Clinical Effectiveness Group who also support based on the QIA risk scores and EIA.

The context of this recommendation is that availability of GF foods has increased since the original policies were implemented, and whilst the cost of GF bread and bread mixes is still higher, some GF products (e.g. pasta) is the same price. Food labelling is much improved supporting patients to make healthy choices, and in addition, this is not a prescribed medication and bread and bread mixes are not considered an essential food item.

In addition, the withdrawal of prescribing of GF foods has already been implemented in St Helens and part of Cheshire West and so far, we are unaware of any unforeseen consequences; and NHS Cheshire and Merseyside do not prescribe products for other food alternatives for other food allergy / intolerances.

It should be noted that 99% of GF prescriptions issued are subject to payment exemption, the reason for the majority (73%) is that of age. A number of our ICB neighbours including Lancashire and South Cumbria and Shropshire, Telford and Wrekin have already stopped prescribing.

In accordance with the framework methodology established as part of the decommissioning policy, this has been undertaken for Gluten Free prescribing and the output is as follows:

The combined impact of the individual criterion scores, when put through the Prioritisation Framework tool is an overall score of 4.86. This equates to an overall assessment of "Consider Decommission / discontinue" indicating that this investment carries a relatively low priority within the context of financial recovery. (see appendix G).

The options appraisal paper was initially discussed with the Associate Directors of Quality where the proposal was acknowledged and supported. It was subsequently presented to the Recovery Committee on 16th September and was then considered by the Strategy and Transformation (S&T) committee at the meeting on 19th September. The S&T committee supported the recommendation to present the preferred option, to cease prescribing to the Board and that we progress to a public consultation to inform the outcome.

The recommendation to withdraw prescribing is also supported by the Recovery Committee and the Strategy and Transformation Sub-Committee based on the financial case and the QIA and EIA feedback. It is of note that the options appraisal was also reviewed and considered by the Clinical Effectiveness Group on 2nd October and the group supported progress of the proposed option to withdraw prescribing across Cheshire and Merseyside.

6.1 The Ask:

The Board are asked to:

- **approve** the recommendation put forward by the Reducing Unwarranted Variation Steering Group and supported by the Recovery Committee and Strategy and Transformation sub-committee to progress a proposal for a non-prescribing option for gluten free bread and bread mixes in order to commence a public consultation starting in January 2025. The feedback from this exercise, together with that of our Oversight and Scrutiny Committees will inform the decision whether to continue with this recommended option.

Appendices

Appendix A – EIA for option 2 – prescribe across all Places



Appendix A EIA
Clin070 GlutenFree S1

Appendix B – EIA for option 3 – stop prescribing across all Places



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Appendix C – QIA for option 2 – prescribe across all Places



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M%20ICB%20QIA%20

Appendix D – QIA for option 3 – stop prescribing across all Places



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HS%20Cheshire%20a

Appendix E – National Gluten Free Prescribing Offers (where available)

<https://westcheshireway.glasscubes.com/share/s/62deuiccpflvuqvc4kedtu31qo>

Appendix F – DHSC EIA

https://assets.publishing.service.gov.uk/media/5a823231e5274a2e87dc1a59/Equality_impact_assessment_-_GF_food.pdf

Appendix G – NHC C&M Decommissioning Framework review

<https://westcheshireway.glasscubes.com/share/s/ku6ksdqu610ekti92nuci6rj07>

<https://westcheshireway.glasscubes.com/share/s/v8q9qa836ob739m35697hq4d1e>

Gluten-free prescribing proposal

Draft plan for public consultation

Introduction and background

Gluten free (GF) products are sometimes prescribed to individuals who suffer from coeliac disease.

Updated national guidance on prescribing of GF products was introduced in 2018, with the intention of reducing previous variation in what was prescribed. The new guidance meant that GF products that fell outside the category of a bread or a mix were no longer prescribed at NHS expense. Local commissioners were encouraged to align their local policies with the amended regulations, but could also choose to restrict further by selecting bread only, mixes only or choose to end prescribing of all GF foods, if they felt this was appropriate for their population.

As the successor body to nine former clinical commissioning groups (CCGs), NHS Cheshire and Merseyside inherited each CCG's commissioning policies, including those for GF prescribing. Currently, there is not a single approach to prescribing of GF products across Cheshire and Merseyside. Seven areas or 'Places' (Cheshire East, Halton, Knowsley, Liverpool, Sefton, Warrington and Wirral) offer gluten free bread and bread mixes on prescription to eligible patients, while St Helens and Cheshire West do not offer this (although there are still some parts of Cheshire West where prescribing is undertaken – Winsford, Northwich, Middlewich and surrounding area).

On 28 November 2024, the Board of NHS Cheshire and Merseyside will be asked to give the go-ahead for a public consultation about a proposal to end ICB funded gluten free prescribing across Cheshire and Merseyside.

This document outlines NHS Cheshire and Merseyside's plan for holding a public consultation on this proposal from 14 January to 25 February 2025, pending the Board's approval. It should be read alongside the following paper being presented to Board: *Proposal for ICB funded Gluten Free Prescribing across Cheshire and Merseyside*, which contains additional background and rationale for the proposed change.

Objectives

The public consultation will present a single option – the cessation of GF prescribing across Cheshire and Merseyside. The objectives of the consultation are:

- To inform patients, carers/family members, key stakeholders, and the public of proposed changes to gluten free prescribing.
- To engage with people who currently receiving gluten free bread and bread mixes on prescription, organisations which support them (where applicable), their carers/family members, and the wider public, to gather people's views about the proposed changes, including how individuals might be impacted.

- To use these responses to inform final decision-making around the proposal.

Legal and statutory context

The main duties on NHS bodies to make arrangements to involve the public are set out in the National Health Service Act 2006, as amended by the Health and Care Act 2022 (section 14Z45 for integrated care boards).

Involvement also has links with separate duties around equalities and health inequalities (section 149 of The Equality Act 2010 and section 14Z35 of the National Health Service Act 2006). As part of our work, we need to involve people with protected characteristics, social inclusion groups and those who experience health inequalities.

The courts have established guiding principles for what constitutes a fair consultation exercise, known as the Gunning principles. These are:

1. Consultation must take place when the proposal is still at a formative stage.
2. Sufficient information and reasons must be put forward for the proposal to allow for intelligent consideration and response.
3. Adequate time must be given for consideration and response.
4. The product of consultation must be conscientiously taken into account.

Methods of engagement and materials

NHS Cheshire and Merseyside will produce clear and accessible public-facing information about the proposal, details of who is likely to be impacted and how, setting out the background to the issue and explaining why NHS Cheshire and Merseyside is proposing to make a change.

This information will be accompanied by a questionnaire containing both qualitative and quantitative questions, designed to gather people's views and perspectives on the proposals. Both the information and questionnaire will be available in Easy Read format. All materials will be made available on the NHS Cheshire and Merseyside website, with printed versions and alternative formats/languages available on request (via email or telephone). People who are unable to complete the questionnaire will be able to provide their feedback over the telephone.

The consultation will be promoted across NHS Cheshire and Merseyside's internal and external communication channels. Wider partners and stakeholders, including providers of NHS services (hospitals, community and mental health providers and primary care), local authorities, Healthwatch, and voluntary, community, faith and social enterprise (VCFSE) organisations, will be asked to share information using their own channels, utilising a toolkit produced for this purpose.

To ensure that those who would be most impacted by any potential change have an opportunity to share their views, NHS Cheshire and Merseyside will seek to work with colleagues in general practice and local pharmacies, to ensure that those who currently receive gluten free bread and bread mixes on prescription are made aware that the consultation is underway.

While specific events will not be organised as part of the consultation, if individual groups/networks request further information, NHS Cheshire and Merseyside will offer to attend meetings to provide additional briefings if required/appropriate.

Audiences

The following is an overview of key groups who we will seek to engage and/or communicate with during the consultation, either as a party with a direct interest or as a means of promoting the consultation to a wider audience.

Internal/NHS

- NHS Cheshire and Merseyside Integrated Care Board (ICB)
- NHS C&M staff
- General practice
- Primary care networks (PCNs)
- Local medical committees
- Local pharmacy committees
- NHS England

External

- General public in Cheshire and Merseyside
- People in Cheshire and Merseyside who currently receive prescriptions for GF bread and bread mixes (approx. 2,300)
- Local authorities
- Champs Public Health Collaborative
- MPs
- Local voluntary, community, faith and social enterprise organisations (VCFSEs)
- Local Healthwatch organisations
- Local/regional media outlets
- Coeliac UK (Liverpool, Cheshire and Warrington branches)

Governance and approvals

This plan has been developed by NHS Cheshire and Merseyside's Communications and Engagement team, which will also be responsible for leading public consultation activity. The plan will be presented to the Board of NHS Cheshire and Merseyside for approval before consultation commences.

Local authority scrutiny

NHS commissioners must consult local authorities when considering any proposal for a substantial development or variation of the health service. Subject to the board's approval of this plan, NHS Cheshire and Merseyside will commence discussions with each of the relevant local authorities.

Responding to enquiries

Members of the public will be directed to contact engagement@cheshireandmerseyside.nhs.uk with any enquiries about the consultation (a phone number will also be supplied). NHS Cheshire and Merseyside's Patient Experience

Team will be briefed on the engagement so that any enquiries that come through central routes can be directed appropriately.

Analysis, reporting and evaluation

When the consultation closes, the findings will be analysed and compiled into a report by an external supplier. The feedback received will be used to inform final decision-making about the proposal, and will therefore be received by a future meeting of the Board of NHS Cheshire and Merseyside. The outcome of this will be communicated using the same routes used to promote the consultation.

It's important to understand the effectiveness of different routes for reaching people, so that this can be utilised for future activity, and the questionnaire will ask people to state where they heard about the engagement. We will summarise this information – along with other measures such as number of enquiries received and visits to the website page – in the final consultation report.

ENDS

DRAFT



Equality Analysis Report

Pre-Consultation/ Post-Consultation/Full Report* (Use the same form but delete as applicable. If it is post-consultation it needs to include consultation feedback and results)

Cheshire & Merseyside wide

Start Date:	October 2024	
Equality and Inclusion Service Signature and Date:	Nicky Griffiths	30 October 2024
Sign off should be in line with the relevant ICB’s Operational Scheme of Delegation (*amend below as appropriate)		
*Place/ ICB Officer Signature and Date:	Katie Bromley	30 October 2024
*Finish Date:		
*Senior Manager Sign Off Signature and Date		
*Committee Date:	28 th November 2024	

1. Details of service / function:
Guidance Notes: Clearly identify the function & give details of relevant service provision and or commissioning milestones (review, specification change, consultation, procurement) and timescales.
<p>In 2016 – 2017 the Department of Health and Social Care undertook a review of prescribing for gluten free products and following a public consultation recommended that prescribing was limited to bread and bread mixes only.</p> <p>When gluten free prescribing was first introduced, the availability of these foods was limited, however, all major supermarkets and other retailers stock gluten free foods both in store and on-line. In addition, food labelling has improved, and awareness has increased which means people are able identify which foods contain gluten and choose healthy options.</p> <p>Currently in Cheshire and Merseyside 7* out of 9 Places offer Gluten Free Prescribing for patients with diagnosed coeliac disease in line with DHSC guidelines (*St Helens CCG and part of Cheshire West CCG stopped prescribing around 5 years ago). Therefore, there is inequity across Cheshire and Merseyside.</p> <p>NHS Cheshire and Merseyside was created in July 2022 and, as the statutory body, took over commissioning responsibilities from the 9 former CCGS. NHS C&M has to consider how to use the fixed resource allocation from NHS England to enable them to fulfil their</p>

duties and have to decide how and where to allocate resources to best meet the healthcare needs of the population they serve.

Under the Policy Harmonisation programme, and based on the DHSC consultation and clinical opinion, the recommendation was to re-instate prescribing for bread and bread mixes however this would result in an estimated additional annual spend of £130k. However, because of the need for NHS Cheshire and Merseyside to consider how they allocate funding to ensure it is being allocated to areas of highest risk, a review has been undertaken regarding the continuation of spend on gluten free prescribing and a recommendation to Board to stop gluten free prescribing is being presented. This would of course be subject to a public consultation exercise in order to inform the final decision.

A number of other ICBs have stopped prescribing, one of our neighbouring ICBs Lancashire and South Cumbria do not offer this service, and as an ICB we do not prescribe other food products for patients with other food intolerances or allergies.

What is the legitimate aim of the service change / redesign

For example

- Demographic needs and changing patient needs are changing because of an ageing population.
 - To increase choice of patients
 - Value for Money-more efficient service
- Public feedback/ Consultation shows need/ no need for a service
 - Outside commissioning remit of ICB/NHS
-

- To ensure a harmonised approach across Cheshire and Merseyside to prescribing food products for patients with coeliac disease and with other food intolerances / allergies
- To support the ICB to achieve financial savings - stopping prescribing across 8 places which would offer an estimated saving of £525k per year.
- To carry out a public consultation exercise to inform the final decision on gluten free prescribing

2. Change to service.

Currently 7* out of 9 Places offer Gluten free prescribing for bread and bread mixes, St Helens and Cheshire West CCG opted to stop this prior to the DHSC consultation. *For Cheshire West Place, the area that was covered by the former Vale Royal CCG did not opt to withdraw prescribing, and as such there are still part of Cheshire West were prescribing can be undertaken (Winsford, Northwich, Middlewich and surrounding area).

The proposal would stop prescribing across all of Cheshire and Merseyside. This proposal is based on the much wider availability of gluten free goods, which has increased in the 6 years since the DHSC consultation, the clearer food labelling which makes healthy choices easier and whilst bread is still more expensive than non gluten free options, the difference in price has reduced and bread is not required for a healthy diet.

3. Barriers relevant to the protected characteristics

Guidance note: describe where there are potential disadvantages.		
<p>Primarily this will affect patients with coeliac disease and related conditions. However, the eligibility criteria states that gluten free products will be commissioned for patients diagnosed as suffering from established gluten-sensitive enteropathies, including dermatitis herpetiformis and coeliac disease. Other impact on protected characteristic groups will be no different to that on other members of the public who suffer with this disease.</p> <p>Awareness raising about alternative gluten free available foods will be available via GPs.</p> <p>There is no evidence to suggest that any protected group has higher prevalence of gluten intolerance.</p> <p>Diabetics and patients with food allergies are the most immediate comparator where alternative foods are not prescribed by the NHS. Gluten intolerance patients do not need to eat wheat based products to maintain good health.</p> <p>Poorly controlled coeliac disease in pregnancy can increase the risk of developing pregnancy-related complications, such as giving birth to a low birth weight baby. However, if pregnant women adhered to Gluten Free diet and their disease is under control then pregnancy related risk would be similar to pregnant women without coeliac disease. Pregnant women with coeliac disease get advice on managing their condition from both General Practitioners and hospital doctors.</p> <p>Coeliac disease is 3 times more common in women than in men and so any policy changes will affect women more than men.</p> <p>This assessment recognises that advice needs to be given to the public on healthy eating for patients with coeliac disease and we need to particularly reach out to women with healthy eating messages - this may help to mitigate against some patients with coeliac disease may not adhere to gluten free diet.</p> <p>Consideration should also be given to older people (who tend to be less mobile) or less mobile people (e.g. due to physical disability) are more likely to find it difficult to source gluten free foods.</p>		

Protected Characteristic	Issue	Remedy/Mitigation
Age	<p>Coeliac UK have identified that it is key for younger people to have the right diet and have in the past supported stopping prescribing for all but under 18s.</p> <p>According to Coeliac UK, the majority of people are diagnosed from 50 years old</p>	<p>C&M data shows that less than 12% of prescriptions are allocated on the basis of being under 18s, and therefore prescribing to just this group could be</p>

	<p>and it is most common in people aged between 50 – 69 years. C&M data shows that 60% of GF prescriptions are allocated because patients are aged 60 and above and therefore our older age population may feel disadvantaged by stopping prescribing or prescribing for just under 18s.</p> <p>However, although only 11% of gf prescriptions are allocated to children and young people, they are not financially independent, and this data does not take into account their parents' financial capacity.</p> <p>According to Coeliac UK, non-adherence to a gluten free diet puts patients at a higher risk of long-term complications, including osteoporosis, ulcerative jejunitis, intestinal malignancy, functional hyposplenism, vitamin D deficiency and iron deficiency. This could lead to patients requiring additional care and support from NHS.</p> <p>An example given by Coeliac UK states it costs £195 a year per patient to support GF on prescription, but the average cost to the NHS of an osteoporotic hip fracture is £27,000.</p>	<p>seen as discriminatory for the older population.</p> <p>GF products are much more widely available in supermarkets and other outlets both in store and on-line, and improved food labelling means that patients are able to make more informed decisions about a healthy diet. In addition, bread is not necessary for a healthy diet as there are gluten free alternatives e.g. GF pasta, rice, potatoes etc.</p> <p>GP would continue to monitor patients and information is widely available on how to avoid gluten and follow a healthy diet.</p>
<p>Disability (you may need to discern types)</p>	<p>Currently, patients can get free NHS prescriptions if, at the time the prescription is dispensed, they:</p> <ul style="list-style-type: none"> • 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. <p>People with coeliac disease, amongst these groups of people, may therefore be negatively impacted as a result of this proposal.</p> <p>People in this cohort may feel that this has a detrimental effect on their finances and so on their overall quality of life.</p> <ul style="list-style-type: none"> • People with learning difficulties may find the GF labelling confusing and could be at greater risk of not adhering to a GF 	<p>Many supermarkets now have outlets on-line offering home deliveries which would support those with mobility issues to access GF products.</p> <p>GPs could offer prescriptions through the Individual Funding Request (IFR) process if their patient could demonstrate exceptionality.</p> <p>GP would continue to monitor patients</p>

	<p>diet without these products being prescribed.</p> <ul style="list-style-type: none"> • Patient with mobility issues may struggle to get to shops to buy GF foods. 	
Gender reassignment	No greater impact	
Marriage and Civil Partnership	No greater impact	
Pregnancy and maternity	<p>Poorly controlled coeliac disease in pregnancy can increase the risk of developing pregnancy-related complications, such as giving birth to a low-birth weight baby.</p>	<p>Only 0.15% of the prescription exemptions are because of maternity exemption which implies the number of patients impacted is minimal.</p> <p>If pregnant women adhered to Gluten Free diet and their disease is under control then pregnancy related risk would be similar to pregnant women without coeliac disease. Pregnant women with coeliac disease get advice on managing their condition from both GPs and hospital doctors.</p> <p>The prescription exemption applies to pregnant women from the time they are pregnant to one year after either the due date or delivery date. This equality group will have short term effect.</p>
Race	No greater impact	
Religion and belief	No greater impact	

Sex	According to NICE the prevalence in females is higher than in males (0.6% compared to 0.4%). C&M data reflects this with 65% of patients being female. This could result in females being more impacted than men, and they feel that this has a detrimental effect on their finances and so on their overall quality of life.	Food labelling is much improved and supports people to make healthy choices. In addition, bread is not necessary for a healthy diet as there are gluten free alternatives e.g. GF pasta, rice, potatoes etc. There are many websites with information on how to remain GF. GP would continue to monitor patients
Sexual orientation	No greater impact	
<p>Whilst currently out of scope of Equality legislation it is also important to consider issues relating to socioeconomic status to ensure that any change proposal does not widen health inequalities. Socioeconomic status includes factors such as social exclusion and deprivation, including those associated with geographical distinctions (e.g. the North/South divide, urban versus rural). <i>Examples of groups to consider include: refugees and asylum seekers, migrant, unaccompanied child asylum seekers, looked-after children/ care leavers, homeless people, prisoners and young offenders, veterans, people who live in deprived areas, People living in remote, and rural locations.</i></p> <p style="text-align: center;"><i>Health inclusion groups</i></p> <p style="text-align: center;">https://www.england.nhs.uk/about/equality/equality-hub/national-healthcare-inequalities-improvement-programme/what-are-healthcare-inequalities/inclusion-health-groups/</p> <p style="text-align: center;"><i>For a more in-depth assessment of health inequalities please use the HEAT toolkit</i></p> <p style="text-align: center;">https://www.gov.uk/government/publications/health-equity-assessment-tool-heat</p>		
refugees and asylum seekers	No greater impact	
Looked after children and care leavers	Children and young people in care are not financially independent and often rely on GF specific products.	
Homelessness	No greater impact	
worklessness	No greater impact	
People who live in deprived areas	No greater impact	
carers	No greater impact	
Young carers	No greater impact	
People living in remote, rural and island locations	There is a risk that people in more remote areas will not have the same access to	Many supermarkets offer on-line shopping and deliver to homes,

	supermarkets with gluten free alternatives to bread. People in this cohort may feel that this has a detrimental effect on their finances and so on their overall quality of life.	and bread is not necessary for a healthy diet as there are gluten free alternatives e.g. GF pasta, rice, potatoes etc. GP would continue to monitor patients
People with poor literacy or health Literacy	No greater impact	
People involved in the criminal justice system: offenders in prison/on probation, ex-offenders.	No greater impact	
<i>Sex workers</i>	No greater impact	
People or families on a low income	There is a risk that people or families on low income will not be able to adhere to a gluten free diet because the cost of GF bread and bread mixes compared to a standard loaf and flour is higher. People on 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. The financial capacity of patients over 60 receiving prescription payment exemptions due to age is unknown and therefore still a risk that they will be impacted because of low income. Children and young people are at risk from not being able to adhere to a GF diet if the cost is too expensive. According to Coeliac UK a weekly gluten free food shop can be as much as 20% more expensive than a standard weekly food shop	C&M data shows that less than 2% of the prescription exemptions are because the patient is in receipt of tax credit or income based job seekers allowance. Whilst the cost of bread and flour is more expensive, there are other GF products e.g. pasta which is the same price as standard, and there are other natural GF foods. There are websites with information on how to maintain a GF diet. GP would continue to monitor patients
People with addictions and/or substance misuse issues	No greater impact	
SEND / LD	No greater impact	
Digital exclusion	No greater impact	

4. What data sources have you used and considered in developing the assessment?
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NHS England Guidance: 'Prescribing Gluten-Free Foods in Primary Care: Guidance for CCGs' NICE guidance regarding coeliac disease: https://www.nice.org.uk/guidance/qs134 , Department of Health & Social Care website, Coeliac UK website, C&M prescribing data
5. Involvement: consultation/ engagement
Guidance note: How have the groups and individuals been consulted with? What level of engagement took place? (If you have a consultation plan insert link or cut/paste highlights)
No engagement has taken place yet as the work to date has been an options appraisal to recommend an ICB proposal. This EIA is part of paper to ICB Board meeting to establish support for a non-prescribing option and at that point, if appropriate, public consultation would be initiated in order to inform the final decision.
6. Have you identified any key gaps in service or potential risks that need to be mitigated
Guidance note: Ensure you have action for who will monitor progress. Ensure smart action plan embeds recommendations and actions in Consultation, review, specification, inform provider, procurement activity, future consultation activity, inform other relevant organisations (NHS England, Local Authority).

Risk	Required Action	By Who/ When
<p>If the option to withdraw prescribing is accepted, there is a risk that patients who previously received prescriptions will not adhere to a GF diet which could have significant health implications for them and will potentially increase demand (& cost) on future NHS Services.</p> <p>An example given by Coeliac UK states it costs £195 a year per patient to support GF on prescription, but the average cost to the NHS of an osteoporotic hip fracture is £27,000.</p>	<p>A published DHSC Impact Assessment examines the issue of adherence in detail and concludes that adherence to a GF diet cannot be isolated to any single cause. Evidence shows that many factors are at play including product labelling, cost and information when eating out and managing social occasions. Adherence requires a range of knowledge and skills to avoid all sources of gluten. Gluten free foods are now much more readily available in supermarkets, with clear gluten free labelling and greater awareness on healthy eating choices. Whilst bread and bread mixes are still more expensive than non GF products (according to Coeliac UK a gluten free loaf of bread is on average 4.3 times more expensive than a standard gluten containing loaf) it can be said that the cost of these products has been reducing over time and there are other GF products that are comparable prices to standard goods (e.g.500g of GF pasta is the same price as 500g of pasta containing gluten). In</p>	<p>Medical Directorate would ensure this happened following a decision</p>

	<p>addition, there are naturally free gluten free products e.g. rice, potatoes.</p> <p>In C&M the majority of patients receiving GF Prescriptions are exempt from charges, with over 70% of this being due to age. Because this exemption does not take into account financial capacity it is difficult to evidence what the individual financial impact on the impacted patients would be. It should be noted that there are less than 2% of prescription exemptions identified as being on tax credits or income support.</p> <p>If the option to stop prescribing was accepted, information on how to adhere to a gluten free diet would be made available and GPs would continue to monitor these patients as usual.</p>	
<p>There is a reputational risk to the ICB if the option to withdraw prescribing is accepted. Due to the current cost of living, there have been a number of national articles on the increased cost of “free from” foods despite them being much more available. In addition, 99% of the cohort of patients receiving prescriptions have an exemption in that they do not pay for prescriptions so could be seen that we are disadvantaging our most vulnerable population.</p>	<p>See above regarding non-GF options.</p> <p>In addition, the ICB does not prescribe for other conditions that are associated with, or affected by the types of food they eat, so this would result in a fairer approach for these patients.</p> <p>A public consultation exercise would be held in those Places who currently prescribe in line with the approach taken in St Helens and West Cheshire CCG before a final decision is made.</p>	<p>n/a</p>

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<p>7. Is there evidence that the Public Sector Equality Duties will be met (give details) Section 149: Public Sector Equality Duty (review all objectives and relevant sub sections)</p>		
<p>PSED Objective 1: Eliminate discrimination, victimisation, harassment and any unlawful conduct that is prohibited under this act: (check specifically sections 19, 20 and 29)</p>		
<p>PSED Objective 2: Advance Equality of opportunity. (check Objective 2 subsection 3 below and consider section 4)</p>		
<p>Analysis post consultation</p>		
<p>PSED Objective 2: Section 3. sub-section a) remove or minimise disadvantages suffered by people who share a relevant protected characteristic that are connected to that characteristic.</p>		
<p>Analysis post consultation</p>		
<p>PSED Objective 2: Section 3. sub-section b) take steps to meet the needs of people who share a relevant protected characteristic that are different from the needs of people who do not share it</p>		
<p>Analysis post consultation</p>		
<p>PSED Objective 2: Section 3. sub-section c) encourage people who share a relevant protected characteristic to participate in public life or in any other activity in which participation by such people is disproportionately low.</p>		
<p>Analysis post consultation</p>		
<p>PSED Objective 3: Foster good relations between persons who share a relevant protected characteristic and persons who do not share it. (consider whether this is engaged. If engaged consider how the project tackles prejudice and promotes understanding -between the protected characteristics)</p>		
<p>Analysis post consultation</p>		
<p>Health Inequalities: Have regard to the need to reduce inequalities between patients in access to health services and the outcomes achieved (s.14T);</p>		
<p>[ENTER RESPONSE HERE]</p>		
<p>PSED Section 2: Consider and make recommendation regards implementing PSED in to the commissioning process and service specification to any potential bidder/service provider (private/ public/charity sector)</p>		
<p>Analysis post consultation</p>		
<p>8. Recommendation to Board</p>		
<p>Guidance Note: will PSED be met?</p>		
<p>[ENTER RESPONSE HERE]</p>		
<p>9. Actions that need to be taken</p>		
<p>[ENTER RESPONSE HERE]</p>		

QUALITY IMPACT ASSESSMENT					
Project Name	Gluten Free Prescribing – Option 3 All Places Withdraw Gluten Free Prescribing				
Verto/PMO reference		Date of QIA	10/07/24	Date QIA reviewed	Stage 1 (local) 21/08/2024
					Stage 2 (regional) 06/09/24
Name of Project Manager	Katie Bromley	Name of Programme manager	Natalia Armes	Clinical Lead	Rowan Pritchard Jones
Confirm date discussed at PDG or appropriate Place forum	n/a ICB Wide Recovery Programme	Is this QIA part of an options appraisal?	Yes	Is the place of care expected to change?	n/a
Is this a permanent or temporary change? (e.g., a GRANT or a PILOT scheme?)	Permanent	If temporary – what are the expected timescales?	n/a	What will happen to the cohort of patients in progress when the service ends?	They will have to fund their own Gluten Free products
It is a nationally, or regionally, mandated service?	No	Is it identified as clinically essential?	No	Is it a statutory service? Y/N and details	No
Confirm if a Digital Impact Assessment has been undertaken	n/a	Confirm if a DPIA is required. (Remember this on all the data involved – not just the data held by NHS C&M)	n/a	An EIA is advised. Confirm if it has been undertaken.	Yes
Number of patients affected	2570 (23/24 data)	Mitigated quality risk if project progresses.	Moderate - 4	Mitigated Quality risk if project is NOT Progressed	Low - 1
Current costs	£520,000	Proposed costs	£0	Does it impact on another C&M Place?	8 of 9 Places: Liverpool Wirral Sefton

					Knowsley Warrington Halton Cheshire East Cheshire West (excluding GP practices in Cheshire West CCG footprint)
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Background and overview of the proposals (can be copied from PID on Verto or from National/Regional commissioning guidance)

In 2016 – 2017 the Department of Health and Social Care undertook a review of prescribing for gluten free products and following a public consultation recommended that prescribing was limited to bread and bread mixes only. When gluten free prescribing was first introduced, the availability of these foods was limited, however, all major supermarkets and other retailers stock gluten free foods both in store and on-line. In addition, food labelling has improved, and awareness has increased which means people are able identify which foods contain gluten and choose healthy options.

Currently in Cheshire and Merseyside 7* out of 9 Places offer Gluten Free prescribing for patients with diagnosed coeliac disease in line with the national Department of Health and Social Care (DHSC) consultation the outcome of which was to reduce prescribing to bread and bread mixes only in 2018. It is of note that for the remaining 2 Places, St Helens CCG and Cheshire West CCG opted to withdraw prescribing completely (noting this was prior to the national Department of Health and Social Care (DHSC) consultation as detailed above).

*For Cheshire West Place, the area that was covered by the former Vale Royal CCG did not opt to withdraw prescribing, and as such there are still part of Cheshire West were prescribing can be undertaken (Winsford, Northwich, Middlewich and surrounding area. Therefore, there is inequity of access to these products across Cheshire and Merseyside.

NHS Cheshire and Merseyside was created in July 2022 and, as the statutory body, took over commissioning responsibilities from the 9 former CCGs. NHS C&M has to consider how to use the fixed resource allocation from NHS England to enable them to fulfil their duties and have to decide how and where to allocate resources to best meet the healthcare needs of the population they serve.

Under the Policy Harmonisation programme, and based on the DHSC consultation and clinical opinion, the recommendation was to re-instate prescribing for bread and bread mixes however this would result in an estimated additional annual spend of £130k. However, because of the need for NHS Cheshire and Merseyside to consider how they allocate funding to ensure it is being allocated to areas of highest risk, a review has been undertaken regarding the continuation of spend on gluten free prescribing and a recommendation to Board to stop gluten free prescribing is being presented. This would of course be subject to a public consultation exercise in order to inform the final decision.

The purpose of the QIA is to help articulate the risks to patients as it is hard to evidence the impact of withdrawing Gluten Free prescribing.

Risks if the project did not go ahead.

If this option was not supported, this would leave unwarranted variation in access to these services.

<p>Please confirm the specific patient groups affected.</p> <p>Advise the impact on health inequalities</p>	<p>There are over 13,300 patients diagnosed with Coeliac Disease and other conditions which would deem them eligible for gluten free prescribing. Most patients choose to purchase their GF products themselves, however, 2,314 patients receive their GF bread and bread mixes through a prescription.</p> <p>Currently 99% of patients currently receiving Gluten Free prescriptions are exempt from charges. The highest categories are as follows:</p> <ul style="list-style-type: none"> Aged 60 or over – 61% Under 18 – 12% Pre-payment certificate – 3% Medical Exemption – 3% Non specified Declaration – 19% <p>The data shows the biggest impact would be to patients over 60.</p>		
	<p>Positive impact Improved patient safety, such as reducing the risk of adverse events is anticipated</p>	<p>Neutral Impact May have an adverse impact on patient safety. Mitigation is in place or planned to mitigate this impact to acceptable levels</p>	<p>Negative impact Increased risk to patient safety. Further mitigation needs to be put in place to manage risk to acceptable level</p>
<p>Explain how the project minimises the risk of harm and impacts patients. Include any risks</p>	<p>This would save the ICB over £500,000 per annum which could be spent on other priorities.</p>	<p>The majority of patients receiving prescriptions are exempt from charges, and this is mainly due to age. Because this exemption does not take into account financial capacity it is difficult to evidence that these patients would not be able to afford to purchase their own GF bread and mixes. The 2 CCGs that have withdrawn prescribing have advised that they have not experienced an increase in patients presenting with issues relating to not following a GF diet.</p>	<p>It is difficult to evidence the impact of Coeliac patients not being able to access Gluten Free (GF) bread and bread mixes, but there are known risks to not adhering to a GF diet which could have long term health impacts and lead to greater demand on wider health services.</p> <p>According to Coeliac UK, non-adherence to a gluten free diet puts patients at a higher at a higher risk of long-term complications, including osteoporosis, ulcerative jejunitis, intestinal malignancy, functional hyposplenism, vitamin D deficiency and iron deficiency. This could lead to patients requiring additional care and support from NHS.</p>

<p>Explain how the project may impact upon adults at risk and children and provide assurance that safeguarding process are in place with the provider</p>		<p>A gluten free diet may be maintained with items such as potatoes and rice, and bread is not essential</p>	<p>The patient groups that will be most impacted by this decision are older adults (over 60yo) and young people (under 18 & in full time education). These patient groups may potentially be at greater risk (incl. osteoporosis / long term conditions for younger patients) if they do not adhere to a GF diet. It is of note, however, this policy only relates to bread and bread mixes and bread is not an essential food item as there are gluten free alternatives e.g. GF pasta, rice, potatoes etc. and improved labelling on food and website with information on how to maintain a healthy GF diet.</p> <p>Due to the current cost of living, there have been a number of national articles on the cost of “free from” foods despite them being much more available. In addition, 99% of the cohort of patients receiving GF prescriptions have an exemption in that they do not pay for prescriptions so could be seen that we are disadvantaging our most vulnerable population. Because 73% of these exemptions are due to age, and this exemption does not take into account financial capacity, it is difficult to evidence that these patients would not be able to afford to purchase their own GF bread and mixes</p>
<p>Describe the impact on processes for reducing and</p>	<p>n/a</p>	<p>n/a</p>	<p>n/a</p>

QUALITY IMPACT ASSESSMENT

preventing patient harms and Healthcare Associated Infections? (e.g., falls, pressure ulcers, MRSA / CDI, VTE, etc)			
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Clinical Effectiveness			
Please confirm how the project uses the best, knowledge based, research	The review of GF prescribing was carried out initially by Pharmacists and Dieticians, with support from other clinicians as part of the CPH Steering Group and was then continued under the ICB Unwarranted Variation Programme due to the financial constraints. Evidence from Dept. Health & Social Care, Coeliac UK was also reviewed. The recommendation from DH&SC is now to prescribe only bread and bread mixes, however, in the “Prescribing Gluten-Free Foods in Primary Care: Guidance for CCGs” document, published following the consultation in 2018 it does state “CCGs may further restrict the prescribing of GF foods by selecting bread only, mixes only or CCGs may choose to end prescribing of GF foods altogether”.		
	Positive impact Clinical effectiveness will be improved resulting in better outcomes anticipated for patients	Neutral impact May have an adverse impact on clinical effectiveness. Mitigation is in place or planned to mitigate this impact to acceptable risk levels	Negative impact Significant reduction in clinical effectiveness. Further mitigation needs to be put in place to manage risk to acceptable level
Explain if/how the project improves hospital flow or improves length of stay		These patients would not be treated in a hospital environment, so no impact on length of stay.	
Describe the impact on			It is difficult to evidence the impact of Coeliac patients not being able to access

<p>clinical outcomes and how this will be monitored.</p>			<p>GF bread and bread mixes, but there are known risks to not adhering to a GF diet which could have long term health impacts (e.g. osteoporosis, ulcerative jejunitis, intestinal malignancy, functional hyposplenism, vitamin D deficiency and iron deficiency), and lead to greater demand on wider health services. However, availability of gf products has improved, as has food labelling. Patients would continue to be supported by their GPs as usual.</p> <p>Feedback from the 2 CCGs who have withdrawn prescribing have not reported any unforeseen consequences.</p>
<p>Does the project result in a higher likelihood of clinical recovery?</p>			<p>If patients cannot afford or cannot get to a supermarket to buy their own GF bread and bread mixes, there could be a negative impact on their long term health.</p>
<p>Does the project provide better access to wider care pathways?</p>			<p>No this would end prescribing</p>
<p>Does the project follow the latest NICE guidance/other relevant best practice evidence?</p>			<p>No. DH&SC and Coeliac UK guidance recommend prescribing bread and bread mixes</p>
<p>Describe the feedback of clinical leads</p>	<p>A number of clinicians have expressed support for the withdrawal, some noting that they have seen requests reduce over the last couple of years potentially due to wider availability of GF products in shops.</p>	<p>Where Clinical Leads support the withdrawal of prescribing, they have noted a potential financial impact to lower income patients.</p>	<p>The Dieticians who were part of the Clinical Policy Harmonisation programme did not support stopping prescribing through concern over those patients who may not follow a GF diet if not prescribed. However, feedback from those Places who have withdrawn</p>

			prescribing is that they have not experienced unforeseen consequences. GPs would continue to support patients and information on how to maintain a GF diet is widely available
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Patient Experience			
Please confirm the specific patient groups affected and how they are impacted.	A policy not to prescribe gluten free products may have an impact on vulnerable patients because gluten free products, while readily available in supermarkets, are more expensive than standard products, and some patients may not be able to access supermarkets easily.		
	Positive impact Improved patient and carer experience anticipated	Neutral impact May have an adverse impact on patient and carer experience. Mitigation is in place or planned to mitigate this impact to acceptable risk levels	Negative impact Significant reduction in patient and carer experience. Further mitigation needs to be put in place to manage risk to acceptable levels
Explain how the project will impact on the experience of care and better access to services	Not prescribing GF products will save over £500k which can be invested in other services. In addition, GF products are also the only food product that is offered on prescription, but there are other food allergies that don't have this offer, so could argue that stopping prescribing further reduces unwarranted variation.	This option withdraws prescribing and therefore does not impact access to services, however for patients who currently receive prescriptions they may reflect that experience of care is impacted by this, but access to supporting services is unchanged.	

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Describe any consultation or engagement with the population that has occurred or is planned.		Public consultation would take place following a decision from the ICB Board as to whether withdrawing prescriptions would be considered	
Describe any change of location or setting of care.	n/a	n/a	n/a

Have any risks been identified in the following areas? (please list risk and escalation process)				
Area	Risk identified	If escalated, identify where escalated to	Date escalated	Mitigations put in place
Staff Experience	no			
Service Delivery	no			
Disinvestment	no			
Contingency plans	no			
Interdependency	no			
Sustainability	no			

QUALITY IMPACT ASSESSMENT

RISKS where the project is progressed				
	Comment to explain rationale (include mitigations where applicable)	Likelihood of risk (L) (see table below)	Risk Impact / Consequence (C) (see table below)	Multiplication Total L x C
Quality risk to progress project	If the option to withdraw prescribing is accepted, there is a risk that patients who previously received prescriptions will not adhere to a GF diet due to affordability of free from products, which could have significant health implications for them and will potentially increase demand on health services as a result. There is a risk that this will widen health inequalities in deprived areas.	2	3	6
MITIGATED RISK to progress project				
Quality risk to progress project	<p>In line with Cheshire West CCG actions when they stopped prescribing, we would improve the information and advice available to patients with coeliac disease that will help them to have a healthy, nutritious and balanced diet with all the necessary vitamins and minerals.</p> <p>Coeliac patients can still eat all naturally gluten-free foods such as meat, fish, fruit, vegetables, rice, and potatoes. We will provide advice to the following:</p> <p>Coeliac UK website for guidance and advice NHS Choices Website BBC website on gluten free diet The Eatwell Guide - NHS).</p> <p>Engage with supermarkets within C&M footprint to advise of prescribing decision with ask of them to manage their stock levels.</p>	2	2	4

RISKS if project is NOT progressed				
	Comment to explain rationale (include mitigations where applicable)	Likelihood of risk (L)	Risk Impact / Consequence (C)	Multiplication Total for not progressing project

QUALITY IMPACT ASSESSMENT

		See table below	See table below	L x C
Quality risk if project does not proceed	<p>If the option to withdraw prescribing is not supported, then C&M have unwarranted variation in access to these products.</p> <p>The alternative option is to re-instate prescribing, however, there is a financial risk to the ICB in that an additional £130k would be required to support this and a total estimated annual expenditure of £650k.</p>	1	1	1
MITIGATED RISK if project is NOT progressed				
Mitigated quality risk to progress project	Place based Medicines Management teams would review prescribing quantities to ensure they are in line with Coeliac UK guidance. This may mitigate some of the cost.	1	1	1

Summary

Decision made	Score	Mitigated score	Impact
Progress	6	4	moderate
Not progress	1	1	Low
Score summary (add to front page)			
Negligible and Low risk	Moderate risk	Major risk	Catastrophic risk
1-3	4 to 6	8- 12	13- 25

Risk Impact Score Guidance

LEVEL	DESCRIPTOR	DESCRIPTION – ICB LEVEL
5	Catastrophic (>75%)	<p>Safety - multiple deaths due to fault of ICB OR multiple permanent injuries or irreversible health effects OR an event affecting >50 people.</p> <p>Quality – totally unacceptable quality of clinical care OR gross failure to meet national standards.</p> <p>Health Outcomes & Inequalities – major reduction in health outcomes and/or life expectancy OR major increase in health inequality gap in deprived areas or socially excluded groups</p> <p>Finance – major financial loss - >1% of ICB budget OR 5% of delegated place budget</p> <p>Reputation – special measures, sustained adverse national media (3 days+), significant adverse public reaction / loss of public confidence major impact on trust and confidence of stakeholders</p>
4	Major (50% > 75%)	<p>Safety - individual death / permanent injury/ disability due to fault of ICB OR 14 days off work OR an event affecting 16 – 50 people.</p> <p>Quality – major effect on quality of clinical care OR non-compliance with national standards posing significant risk to patients.</p> <p>Health Outcomes & Inequalities – significant reduction in health outcomes and/or life expectancy OR significant increase in health inequality gap in deprived areas or socially excluded groups</p> <p>Finance - significant financial loss of 0.5-1% of ICB budget OR 2.5-5% of delegated place budget</p> <p>Reputation - criticism or intervention by NHSE/I, litigation, adverse national media, adverse public significant impact on trust and confidence of stakeholders</p>
3	Moderate (25% > - 50%)	<p>Safety - moderate injury or illness, requiring medical treatment e.g., fracture due to fault of ICB. RIDDOR/Agency reportable incident (4-14 days lost).</p> <p>Quality – significant effect on quality of clinical care OR repeated failure to meet standards</p> <p>Health Outcomes & Inequalities – moderate reduction in health outcomes and/or life expectancy OR moderate increase in health inequality gap in deprived areas or socially excluded groups</p> <p>Finance - moderate financial loss - less than 0.5% of ICB budget OR less than 2.5% of delegated place budget</p>

		<p>Reputation - conditions imposed by NHSE/I, litigation, local media coverage, patient and partner complaints & dissatisfaction moderate impact on trust and confidence of stakeholders</p>
2	Minor (<25%)	<p>Safety - minor injury or illness requiring first aid treatment</p> <p>Quality – noticeable effect on quality of clinical care OR single failure to meet standards</p> <p>Health Outcomes & Inequalities – minor reduction in health outcomes and/or life expectancy OR minor increase in health inequality gap in deprived areas or socially excluded groups</p> <p>Finance - minor financial loss less than 0.2% of ICB budget OR less than 1% of delegated place budget</p> <p>Reputation - some criticism slight possibility of complaint or litigation but minimum impact on ICB minor impact on trust and confidence of stakeholders</p>
1	Negligible (<5%)	<p>Safety - none or insignificant injury due to fault of ICB</p> <p>Quality – negligible effect on quality of clinical care</p> <p>Health Outcomes & Inequalities – marginal reduction in health outcomes and/or life expectancy OR marginal increase in health inequality gap in deprived areas or socially excluded groups</p> <p>Finance - no financial or very minor loss</p> <p>Reputation - no impact or loss of external reputation</p>

The likelihood of the risk occurring must then be measured. Table 2 below should be used to assess the likelihood and obtain a likelihood score. When assessing the likelihood, it is important to take into consideration the existing controls (i.e. mitigating factors that may prevent the risk occurring) already in place.

Table 2 - Risk Likelihood Score Guidance

1	2	3	4	5
<p>Rare The event could only occur in exceptional circumstances (<5%)</p>	<p>Unlikely The event could occur at some time (<25%)</p>	<p>Possible The event may well occur at some time (25%> -50%)</p>	<p>Likely The event will occur in most circumstances (50% > 75%)</p>	<p>Almost certain The event is almost certain to occur (>75%)</p>

QUALITY IMPACT ASSESSMENT

The impact and likelihood scores must then be multiplied and plotted on table 3 to establish the overall level of risk and necessary action.

Table 3 - Risk Assessment Matrix (level of risk)

LIKELIHOOD of risk being realised	IMPACT (severity) of risk being realised				
	Negligible (1)	Minor (2)	Moderate (3)	Major (4)	Catastrophic (5)
Rare (1)	1	2	3	4	5
Unlikely (2)	2	4	6	8	10
Possible (3)	3	6	9	12	15
Likely (4)	4	8	12	16	20
Almost Certain (5)	5	10	15	20	25

Low Risk	Moderate Risk	High Risk	Extreme Risk	Critical Risk
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Risk Proximity

A further element to be considered in the risk assessment process is risk proximity. Risk proximity provides an estimate of the timescale as to when the risk is likely to materialise. It supports the ability to prioritise risks and informs the appropriate response in the monitoring of controls and development of actions.

A pragmatic approach to the use of risk proximity which supports leadership, decision making and reporting is used and is therefore determined to be applied to all Risks.

The proximity scale used is below:

Proximity and timescale for dealing with the risk	Within the current quarter	Within the financial year	Beyond the financial year
Rating	A	B	C

Likelihood, impact and proximity are dynamic elements and consequently all three must be reviewed and reassessed frequently in order to prioritise the response.

Sign off process			
Name	Role	Signature	Date
Katie Bromley	Project lead		4/9/24
Sinead Clarke	Clinical lead		4/9/24
Natalia Armes	Programme manager		4/9/24
	PMO lead		
Once signed off by all above, then the QIA is submitted to QIA review group			

This section to be completed following review at the QIA review group					
Name	Role	Approved	Rejected	Signature	Date
ADs of Quality	QIA review group chair (after group meeting)	Yes			6/9/24
Denise Roberts (supported by Maxine Dickinson)	AD of Quality	Yes			21/08/24
	C&M ICB QIA lead (if necessary)				