

Combined Impact Assessment

To be completed with support from Quality, Equality and Engagement leads; email for all correspondence: wycb-leeds.qualityteam@nhs.net

Complete all sections (see instructions/comments and consider) Impact Matrix on page 9.

Assessment Completion	Name	Role	Date	Email
Scheme Lead	Catherine Thompson	Associate Director Planned Care, NHS West Yorkshire Integrated Care Board (WY ICB). From 1 April 2024, Associate Director, Clinical Policy and Individual Funding Requests (IFR) Function.	16 February 2024	Catherine.thompson13@nhs.net
Programme Lead sign off	David Smith Dr James Thomas	WY ICB, Chief Pharmacist WY ICB Medical Director		David.smith@bthft.nhs.uk James.thomas2@nhs.net

A. Scheme Name	Harmonisation of Commissioning Policies_Harmonising the Prescribing of Gluten Free Products across West Yorkshire (proposal to stop prescribing gluten free products in Calderdale and Leeds)
Type of change	Proposal to stop prescribing gluten free products (GF Products) in Calderdale and Leeds
ICB	West Yorkshire

B: Summary of change - Briefly describe the proposed change to the service, why it is being proposed, the expected outcomes and intended benefits, including to patients, public and ICB finances. Describe in terms of aims; objectives, links to the ICB's strategic plans and other projects, partnership arrangements, policies (national and regional).

Since 2017 the WY Health and Care Partnership, and latterly as the WY ICB, since its formation on 1 July 2022 under the Health and Social Care Act 2022, has been working to harmonise patient access thresholds for healthcare interventions and medicines, and significant progress has been made on this. There remains an inconsistent approach to the funding of NHS prescriptions for GF products within WY ICB. The NHS funding of GF products prescribed for coeliac disease was stopped in Bradford District and Craven in 2016; and Kirklees and Wakefield in 2017 (two separate places across WY). It continued in both Leeds and Calderdale places. **The current exceptionality criteria for Bradford District**

and Craven, and Kirklees, and Wakefield as per the proposed Commissioning Statement for Gluten Free Products for the whole of West Yorkshire and its five places is:

Circumstances where the prescriber believes that in their clinical judgement, exceptional circumstances exist that warrant deviation from the recommendation to not prescribe gluten-free products.

Individual patients where the clinician considers that their ability to self-manage is compromised as a consequence of medical, mental health or significant social vulnerability to the extent that their health and/or wellbeing could be adversely affected, if reliant on self-care. To note that being exempt from paying a prescription charge does not automatically warrant an exception to the guidance. Consideration should also be given to safeguarding issues.

Exceptionality is expected to be very rare and when all other advice and support is unsuitable or has failed such as advice around where gluten free products can be sourced for a reasonable price, advice around food sources that are naturally gluten free, advice around Coeliac UK membership/resources or referral to a dietician. Even in exceptional circumstances only gluten free bread and bread mixes will be available on prescription.

The Integrated Care Board (ICB) Transformation Committee decided on 31 October 2023 to stop routinely commissioning or funding the prescription of gluten free (GF) bread and mixes (“**GF Products**”) in Leeds and Calderdale, bringing them in line with the other places of West Yorkshire.

Since that Transformation Committee, a legal challenge to the Committee’s decision has been threatened. The ICB took a pragmatic decision that, in order avoid the costs and delay that often come with legal proceedings, the ICB would re-consider its decision of 31 October 2023 in relation to the funding of the prescription of GF Products for patients with coeliac disease.

This updated Combined Impact Assessment has been prepared to inform the Transformation Committee’s reconsideration of the proposal to stop prescribing of GF Products (bread and mixes) in Leeds and Calderdale for patients with coeliac disease.

It examines the impact on different patient groups using the available data; and considers potential mitigations and monitoring.

There are a very small number of patients who currently receive low protein GF food on prescription, and they will be unaffected by this change. These patients do not have coeliac disease but have illnesses which require them to eat an extremely restricted diet for which specialist foods are not available on the high street, for example Phenylketonuria (PKU). [Phenylketonuria - NHS \(www.nhs.uk\)](https://www.nhs.uk/conditions/phenylketonuria/)

C. Service Change Details – (Engagement and Equality Checklist) - please describe the impact in each section To be completed in conjunction with Equality Lead; Sharon Moore sharon.moore12@nhs.net and Engagement Lead	Yes/No
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<p>Chris Bridle chris.bridle@nhs.net</p>	
<p>1. Could the project change the way a service is currently provided or delivered?</p> <p>The proposal is to stop funding NHS prescriptions for GF Products in Leeds and Calderdale. The prescribing of Gluten Free products was stopped in Bradford District and Craven in 2016, and both Kirklees and Wakefield WY Places in 2017.</p> <p>Adopting the proposal to withdraw the funding of GF products on prescription would affect around 900 people who are currently in receipt of GF products on prescription (725 people in Leeds, 205 people in Calderdale, approximately) as stated in the two involvement campaigns run in 2023.</p> <p>1st Stage Report: TEMPLATE – WY Involvement report (wypartnership.co.uk)</p> <p>2nd Stage Report: Treatments paid for by NHS stage 2 involvement report Final (wypartnership.co.uk)</p>	<p>Yes</p>
<p>2. Could the project directly affect the services received by patients, carers, and families? –is it likely to specifically affect patients from protected or other groups? see page 10 for more detail</p> <p>As above, patients with coeliac disease will no longer receive NHS funded prescriptions for GF Products.</p> <p>It is likely that those on low incomes will be disproportionately affected by the proposal. Other groups may be disproportionately affected.</p> <p>This proposal affects approximately, 725 people in Leeds and 205 people in Calderdale, who currently receive GF Products through an NHS prescription.</p> <p><u>The first stage report considered the potential impact on particular patient groups. This is set out in detail from page 36 onwards of the report. The report states:</u></p> <p><i>“The equality issues that emerged most strongly was related to age, whether being older or in relation to children, and fewer comments about disability (beyond coeliac disease) and the lack of availability of suitable gluten-free foods, such as chapatis. 87 comments referenced the above issues, some mentioned more than one. There were 30 comments on age, 42 related to children, 12 on disability and 4 related to food options. For younger ages, many mentioned having more than one person in the household requiring gluten-free food.”</i></p> <p><i>Of the 294 people who responded to the patient survey and answered the question: Do you or the person you care for pay for your prescriptions? 79 people answered Yes and 215 people answered No. Those people who don’t pay for their prescription</i></p>	<p>Yes</p>

charges will be impacted more than those people who do pay for their prescription charges. Only 294 people responded to this question out of approximately 900 people who have been identified as being in receipt of GF prescriptions and had been sent the survey to complete via a letter, text or email with a link to the online survey (see page 14 of the involvement report below).

The report on the second stage involvement summarised:

“There was an understanding that we must have consistent policies across West Yorkshire and that the NHS in West Yorkshire needs to make the best use of its limited resources. However, the majority of respondents do not want gluten-free prescribing in Calderdale and Leeds to be stopped. Many respondents stated that coeliac is a disease, not a choice and people living with coeliac disease must follow a gluten-free diet. This would be difficult without having gluten-free products on prescription mainly due to the cost.

Respondents also reported problems with availability of gluten-free products in supermarkets and shops. Some people commented that the quality of these products is not as good as those provided on prescription. Respondents made some suggestions which included: continuing to prescribe for children and vulnerable people; having some form of ‘means testing’; and issuing ‘direct payments’ rather than prescriptions to allow for the price difference between gluten-free products and gluten-containing products.”

Of the 86 respondents to the stage 2 survey, 83 shared their views on the recommendation for gluten-free prescribing: -

Availability and quality of GF products = 20

Cost of GF products and impact on lower incomes = 74

Agree with the recommendation and that the NHS must make best use of limited resources = 10

Suggest a mitigation = 7

3. Could the project directly affect staff? For example, would staff need to work differently / could it change working patterns, location etc.?s it likely to specifically affect staff from protected groups?

Yes

GPs and dieticians will have to explain to patients that they are not able to receive gluten free products on NHS prescription. If the mitigation of annual reviews is adopted, then GPs will be encouraged to carry out annual reviews for patients with coeliac disease.

<p>GPs will be encouraged to carry out routine annual reviews, in accordance with NICE Guidance (National Institute for Health and Care Excellence) https://www.nice.org.uk/guidance/ng20/chapter/Recommendations#monitoring-in-people-with-coeliac-disease which will identify any health needs and will support coeliac patients. Collaborative working across WY ICB colleagues to support primary care colleagues with embedding NICE best practice in clinical management of Coeliac patients and undertaking annual reviews. WY ICB Clinical Policy and IFR (Individual Funding Requests) function to lead this work with place colleagues and primary care colleagues, including GP Leads for places, to support GPs to implement this clinical best practice for Coeliac patients if they have not done so already.</p> <p>Clinical staff in undertaking an evidenced based clinical review of a patient determines the patient has exceptional clinical circumstances, can prescribe GF products on prescription for the patient. That clinical review would be recorded on the patient's medical record. See page 2 above for the exceptionality criteria.</p> <p>Should clinicians identify a number of patients meeting clinical exceptionality criteria this most likely would give cause to review the existing policy or for, any future policy review to consider the exclusion of the affected group, such that they would be prescribed GF products.</p>	
<p>4. Does the project build on feedback received from patients, carers and families, including patient experience? - what feedback and please include links if available.</p> <p>The involvement process has been done in two stages. The first stage was with those people directly affected by the proposed changes to gluten free prescribing. The second stage was wider public involvement asking for feedback on a suite of policies, and inviting comments on particular or specific changes where respondents chose to do so.</p> <p>The full report on the outcome of the first stage involvement exercise can be found here: TEMPLATE – WY Involvement report (wypartnership.co.uk).</p> <p>The full report on the outcome of the second stage involvement exercise can be found here: Treatments paid for by NHS stage 2 involvement report Final (wypartnership.co.uk).</p> <p>Input has also been received from Coeliac UK. Further detail is contained in the report on second stage of involvement.</p> <p>Coeliac UK received the ICB stakeholder briefing about the recommendation for gluten-free prescribing on 25 May 2023 (at stage 1 of involvement). The charity was keen to engage in the review and asked for a meeting to share its insight from the coeliac community. This meeting took place on 27 July 2023 (during stage 2 of involvement).</p>	<p>Yes</p>

<p>Coeliac UK offered a great deal of insight and some suggestions that will be extremely helpful for the next steps. Full details of the discussion at the meeting can be viewed at Appendix B on page 36 of the Stage 2 involvement report. Coeliac UK submitted a formal response on 9 August 2023 to the ICB's engagement on the future of gluten-free prescribing in West Yorkshire: Coeliac UK response to engagement on future of gluten free prescribing (09.08.23).</p> <p>Feedback from meeting with Coeliac UK on 29 August 2023 to discuss the recommendation is included on page 36 of the stage 2 involvement report. This includes a link to Coeliac UK's formal response to engagement on future of gluten free prescribing (09.08.23) which also contains supporting evidence.</p>	
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D: To be completed in conjunction with the Engagement and Equality lead: Insert comments in each section as required	Yes/No
<p>Engagement activity required. Two engagement campaigns were run by the WY ICB in 2023, the first one for Coeliac patients directly affected by the proposal to stop prescribing GF Products in both Calderdale and Leeds TEMPLATE – WY Involvement report (wypartnership.co.uk) and the second one for anyone to comment on the harmonisation of a range of WY ICB Commissioning Policies to address disparity in the patient access thresholds for clinical interventions and medicines, with Gluten Free products being one of them Treatments paid for by NHS stage 2 involvement report Final (wypartnership.co.uk)</p>	<p>Yes (Completed summer 2023)</p>
<p>Formal consultation activity required? The WY ICB contacted the Consultation Institute about the need to consult on the proposal to stop the prescribing of GF Products in both Calderdale and Leeds. Engagement activities were advised but formal consultation was not required.</p>	<p>No</p>
<p>Full Equality Impact Assessment (EIA) required? It has been completed and is provided with this impact assessment.</p>	<p>Yes</p>
<p>Communication activity required (patients or staff)? Both.</p> <p><u>Patients:</u></p> <ul style="list-style-type: none"> • Where WY places stopped the prescribing of GF products in 2016 and 2017, they asked foodbanks to include gluten free foods in their request for donations. • The proposed mitigations for Calderdale and Leeds are: 	<p>Yes</p>

- Signposting patients to alternative products. Other dietary alternatives to gluten free food are available cheaply e.g., rice, potatoes for dietary staples.
- Food banks: working with local foodbanks to promote donations of long life GF products.
- Link in with community groups and the VCSEs.
- Ensuring there is a collated system of information resources for patients.
- Signposting and information: the ICB can produce/ commission information leaflets for patients and prescribers, outlining alternatives to branded GF products (including goods that are naturally GF) and to further information, e.g., from Coeliac UK.

The dietician who wrote to the WY ICB about its proposal to stop prescribing GF products in Calderdale and Leeds, is keen to support coeliac patients across WY and is setting up a working group with dieticians from other places to see how we can provide information and guidance for coeliac patients across WY. One suggestion is to roll out the Bradford Coeliac Disease Newsletter across WY. This work is ongoing.

Staff:

GPs will be encouraged to carry out routine annual reviews, in accordance with NICE Guidance (National Institute for Health and Care Excellence) <https://www.nice.org.uk/guidance/ng20/chapter/Recommendations#monitoring-in-people-with-coeliac-disease> which will identify any health needs and will support coeliac patients.

The dietician who wrote to the WY ICB about its proposal to stop prescribing GF products in Calderdale and Leeds, is keen to support coeliac patients across WY and is setting up a working group with dieticians from other places to see how we can provide information and guidance for coeliac patients across WY. One suggestion is to roll out the Bradford Coeliac Disease Newsletter across WY. This work is ongoing - Engagement between primary care and secondary care, and WY ICB and Place based colleagues, and patients has already commenced.

Collaborative working across WY ICB colleagues to support primary care colleagues with embedding NICE best practice in clinical management of Coeliac patients and undertaking annual reviews - Combination of WY ICB colleagues: Clinical Policy and IFR

<p>function, Pharmacy and Medicine Optimisation Leads, Place planned care and medicines leads, Primary care leads and GP Leads.</p> <p>Monitoring and review of the impact of the proposal will be via data that will inform where we have made changes and implemented mitigations to determine whether those mitigations addressed the negative impact of the change. Feedback from patients and primary care clinicians via surveys and engagement activities will provide the qualitative data for said monitoring and review. The monitoring and review will be undertaken by the WY ICB Clinical and Professional Directorate where prescribing and medicines and clinical policy will sit from 1 April 2024.</p>	
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E. Data Protection Impact Assessment (DPIA) is carried out to identify and minimise data protection risks when personal data is going to be used and processed as part of new processes, systems or technologies.		
<p>Does this project/decision involve a new use of personal data, a change of process or significant change in the way in which personal data is handled? If yes, please email the IG Team at; wycb-leeds.dpo@nhs.net for Leeds ICB or wycb-wak.informationgovernance@nhs.net for the wider WY ICB, to complete the screening form.</p> <p>No DPIA required as does not involve the use of patient personal data in any capacity.</p>	<p>No</p>	

F. Evidence used in this assessment List any evidence which has been used to inform the development of this proposal for example, any national guidance (e.g. NICE, CQC, DoH, Royal Colleges), regional or local strategies, data analysis (e.g. performance data), engagement / consultation with partner agencies, interest groups or patients. Where applicable, state 'N/A' in boxes where no evidence exists, 'Not yet collected' where information has not yet been collected or delete where appropriate	
Evidence Source	Details
Research and Guidance (local, regional, national)	<p>Research</p> <p>Coeliac UK provided evidence about the prevalence, incidence, and nature of coeliac disease as a serious autoimmune disease managed with a gluten free diet. They highlighted the importance of bread as a staple in the British diet and its important role in maintaining iron intake which cannot be achieved through consumption of rice and potatoes. They also provided data about the comparative costs of gluten containing and gluten free staple foods. See further representation from Coeliac UK below.</p>

	<p>As set out above, the ICB undertook an engagement exercise in the summer 2023, details of which are described in the reports linked to above. See sections 1 and 2, and D above.</p> <p>Guidance The ICB has reviewed the best practice recommendations as per NICE Guidance Overview Coeliac disease: recognition, assessment and management Guidance NICE and Coeliac UK Annual review - Coeliac UK.</p> <p>The ICB has reviewed the report of a previous consultation exercise carried out by the Department of Health and Social Care in March 2017 on proposals to make changes to GF prescribing in primary care.</p>
<p>Service delivery data such as who receives services</p>	<p>Coeliac disease affects approximately 1 in 100 of the UK population. For WY ICB this equates to approximately 24,000 people (Total population of WY is approximately 2.4 million). This proposal affects approximately 930 people who are currently in receipt of gluten free products on prescription (725 people in Leeds, 205 people in Calderdale. Data correct on 31 October 2023).</p>
<p>Consultation / engagement</p>	<p>As set out above, involvement was carried out in two stages: (1) those people directly affected by the proposed changes to gluten free prescribing; and (2) wider public involvement. Links to the full reports are set out above.</p> <p><u>We also received input from Coeliac UK.</u></p> <p>Coeliac UK received the ICB stakeholder briefing about the recommendation for gluten-free prescribing on 25 May 2023 (at stage 1 of involvement). The charity was keen to engage in the review and asked for a meeting to share its insight from the coeliac community. This meeting took place on 27 July (during stage 2 of involvement).</p> <p>Coeliac UK offered a great deal of insight and some suggestions that will be extremely helpful for the next steps. Full details of the discussion at the meeting can be viewed at Appendix B on page 36 of the Stage 2 involvement report.</p>

	Coeliac UK submitted a formal response on 9 August 2023 to the ICB's engagement on the future of gluten-free prescribing in West Yorkshire: Coeliac UK response to engagement on future of gluten free prescribing (09.08.23).
Experience of care intelligence, knowledge and insight (Complaints, Compliments, PALS, National and Local Surveys, Friends and Family Test, consultation outcomes)	Since 1 November 2023 WY ICB has received 10 items of feedback relating to the decision to stop providing gluten free products on prescription. One was a formal complaint, and the remaining feedback came through PALS (NHS Patient Advice and Liaison Service). The main objection or concern relating to the decision to stop provision was finance / affordability, with four people citing specific personal financial impact and lack of affordability. Two contributors felt there should be an exception for children, in part due to the social nature of eating and its importance in children's development of personal and social relationships, particularly in younger age groups. One clinical contributor identified a new risk for children with complex allergy, which may prohibit many commercially available gluten free products.
Other	<p>One clinical contributor wrote to the ICB following the 31 October 2023 Transformation Committee and identified a new risk for children with complex allergy, which may prohibit the use of many commercially available gluten free products. The dietitian mentioned above in section D and below, and the clinical contributor are two separate individuals.</p> <p>One dietician contacted the ICB after the patient and public involvement exercise. He described his observations of increasing numbers of people being unable to maintain a gluten free diet because of affordability, since prescribing stopped in previous WY Places in 2016 and 2017. He also highlighted specific concerns for patients of South Asian heritage as maintaining a gluten free diet is more challenging with a traditional South Asian diet. This is in part due to the lack of gluten free chapatis in supermarkets.</p>

G. Impact Assessment: Quality, Equality, Health Inequalities, Safeguarding etc

What is the potential impact on quality of the proposed change? Outline the expected outcomes and who is intended to benefit. Include all potential impacts (positive, negative or neutral).

For negative impacts, list the action that will be taken in mitigation.

See guidance notes on p. 10-11

<p>Quality Domain <i>The list in each domain is not exhaustive; it is illustrative of the type of impact that should be considered. When describing impacts; use words that you consider are meaningful)</i></p>	<p>Quality elements/ Description of impact: <i>Where appropriate provide information about the proposed or current service that contextualises the impact. (Quantify where possible, e.g. number of patients affected)</i> <i>(List & number if more than one in each domain)</i></p>	<p>Impact: Positive / Negative / Neutral & score <i>(Assess each impact using the <u>Impact Matrix</u>; colour cell RAG)</i></p>	<p>What action will you take to mitigate any negative impact? <i>How could the impacts and/or mitigating actions be monitored?</i> <i>Are there any communications or engagement considerations or requirements?</i></p>
<p>1. Patient Safety</p>	<p>1. Some GF foods are more expensive than everyday brands. If people turn to cheaper gluten-containing products, they may suffer health complications.</p> <p>2. Some people with complex co-morbidities such as complex allergy may struggle to maintain adequate dietary intake for health. If they are unable to afford suitable gluten free products other health</p>		<ul style="list-style-type: none"> • Where WY places stopped the prescribing of GF products in 2016 and 2017, they asked foodbanks to include gluten free foods in their request for donations. • The proposed mitigations for Calderdale and Leeds are: <ul style="list-style-type: none"> - Signposting patients to alternative products. Other dietary alternatives to gluten free food are available cheaply e.g., rice, potatoes for dietary staples. - Food banks: working with local foodbanks to promote donations of long life GF products. - Link in with community groups and the VCSEs. - Guidance on best practice of annual reviews for coeliac patients as per NICE guidance to ensure we're managing patients who have specific medical conditions that could be impacted by the proposed change.

conditions may also deteriorate.

- Places to share approach to mitigating actions.

- Ensuring there is a collated system of information resources for patients.

Signposting and information: the ICB can produce/ commission information leaflets for patients and prescribers, outlining alternatives to branded GF products (including goods that are naturally GF) and to further information, e.g., from Coeliac UK

GPs will be encouraged to carry out routine annual reviews, in accordance with NICE Guidance (National Institute for Health and Care Excellence)

<https://www.nice.org.uk/guidance/ng20/chapter/Recommendations#monitoring-in-people-with-coeliac-disease> which will identify any health needs and will support coeliac patients.

On-line options for delivery are available for those patients who have limited mobility or can't buy GF products from their local shops, although buying GF products this way is likely to come with delivery charges.

Clinical staff in undertaking an evidenced based clinical review of a patient determines the patient has exceptional clinical circumstances, can prescribe GF products on prescription for the patient. That clinical review would be recorded on the patient's medical record.

Should clinicians identify a number of patients meeting clinical exceptionality criteria this most likely would give cause to review the existing policy or for, any future policy review to consider the exclusion of the affected group, such that they would be prescribed GF products.

			<p>Monitoring and review of the impact of the proposal will be via data that will inform where we have made changes and implemented mitigations to determine whether those mitigations addressed the negative impact of the change. Feedback from patients and primary care clinicians via surveys engagement activities will provide the qualitative data for said monitoring and review. The monitoring and review will be undertaken by the WY ICB Clinical and Professional Directorate where prescribing and medicines and clinical policy will sit from 1 April 2024.</p>
<p>2. Experience of care</p>	<p>1. People in Leeds and Calderdale will no longer be able to access Gluten Free products on prescription, which they have previously been able to access. This would be against the wishes of people in Leeds and Calderdale expressed in WY ICB consultations.</p> <p>2. People in WY will see other services better maintained / new medicines and services available due to the financial resources released by stopping prescribing of GF products.</p>		<ul style="list-style-type: none"> • Where WY places stopped the prescribing of GF products in 2016 and 2017, they asked foodbanks to include gluten free foods in their request for donations. • The proposed mitigations for Calderdale and Leeds are: <ul style="list-style-type: none"> - Signposting patients to alternative products. Other dietary alternatives to gluten free food are available cheaply e.g., rice, potatoes for dietary staples. - Food banks: working with local foodbanks to promote donations of long life GF products. - Link in with community groups and the VCSEs. - Guidance on best practice of annual reviews for coeliac patients as per NICE guidance to ensure we're managing patients who have specific medical conditions that could be impacted by the proposed change. - Places to share approach to mitigating actions. - Ensuring there is a collated system of information resources for patients. <p>Signposting and information: the ICB can produce/ commission information leaflets for patients and prescribers, outlining alternatives to branded GF</p>

products (including goods that are naturally GF) and to further information, e.g., from Coeliac UK

GPs will be encouraged to carry out routine annual reviews, in accordance with NICE Guidance (National Institute for Health and Care Excellence) <https://www.nice.org.uk/guidance/ng20/chapter/Recommendations#monitoring-in-people-with-coeliac-disease> which will identify any health needs and will support coeliac patients.

On-line options for delivery are available for those patients who have limited mobility or can't buy GF products from their local shops, although buying GF products this way is likely to come with delivery charges.

Clinical staff in undertaking an evidenced based clinical review of a patient determines the patient has exceptional clinical circumstances, can prescribe GF products on prescription for the patient. That clinical review would be recorded on the patient's medical record.

Should clinicians identify a number of patients meeting clinical exceptionality criteria this most likely would give cause to review the existing policy or for, any future policy review to consider the exclusion of the affected group, such that they would be prescribed GF products.

Monitoring and review of the impact of the proposal will be via data that will inform where we have made changes and implemented mitigations to determine whether those mitigations addressed the negative impact of the change. Feedback from patients and primary care clinicians via surveys engagement activities will provide the qualitative data for said monitoring and review. The monitoring and review will be undertaken by the WY ICB Clinical and Professional Directorate where prescribing and medicines and clinical policy will sit from 1 April 2024.

<p>3. Clinical Effectiveness</p>	<p>1. Harmonisation of the prescribing policy for GF will mean patients and people across WY will be treated equitably and have access to the same information and thresholds/criteria, this will support reducing health inequalities, and variation in care.</p> <p>2. Some GF bread and flour mixes are more expensive than everyday brands. If people turn to cheaper gluten-containing products they may suffer health complications and not be able to manage their coeliac disease effectively through diet.</p>		<ul style="list-style-type: none"> • Where WY places stopped the prescribing of GF products in 2016 and 2017, they asked foodbanks to include gluten free foods in their request for donations. • The proposed mitigations for Calderdale and Leeds are: <ul style="list-style-type: none"> - Signposting patients to alternative products. Other dietary alternatives to gluten free food are available cheaply e.g., rice, potatoes for dietary staples. - Food banks: working with local foodbanks to promote donations of long life GF products. - Link in with community groups and the VCSEs. - Guidance on best practice of annual reviews for coeliac patients as per NICE guidance to ensure we're managing patients who have specific medical conditions that could be impacted by the proposed change. - Places to share approach to mitigating actions. - Ensuring there is a collated system of information resources for patients. <p>Signposting and information: the ICB can produce/ commission information leaflets for patients and prescribers, outlining alternatives to branded GF products (including goods that are naturally GF) and to further information, e.g., from Coeliac UK</p> <p>GPs will be encouraged to carry out routine annual reviews, in accordance with NICE Guidance (National Institute for Health and Care Excellence) https://www.nice.org.uk/guidance/ng20/chapter/Recommendations#monitoring-in-people-with-coeliac-disease which will identify any health needs and will support coeliac patients.</p>
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			<p>On-line options for delivery are available for those patients who have limited mobility or can't buy GF products from their local shops, although buying GF products this way is likely to come with delivery charges.</p> <p>Clinical staff in undertaking an evidenced based clinical review of a patient determines the patient has exceptional clinical circumstances, can prescribe GF products on prescription for the patient. That clinical review would be recorded on the patient's medical record. The exceptionality criteria is set out on page 2 above.</p> <p>Should clinicians identify a number of patients meeting clinical exceptionality criteria this most likely would give cause to review the existing policy or for, any future policy review to consider the exclusion of the affected group, such that they would be prescribed GF products.</p> <p>Monitoring and review of the impact of the proposal will be via data that will inform where we have made changes and implemented mitigations to determine whether those mitigations addressed the negative impact of the change. Feedback from patients and primary care clinicians via surveys engagement activities will provide the qualitative data for said monitoring and review. The monitoring and review will be undertaken by the WY ICB Clinical and Professional Directorate where prescribing and medicines and clinical policy will sit from 1 April 2024.</p>
<p>4. Equality</p>	<p>Equality issues are considered in detail in the full EIA.</p>		<p>Equality issues, including potential mitigations of negative impact, are considered in detail in the full EIA.</p>

5. Safeguarding	No impact identified		This is for consideration for the prescribing clinician as set out in the exceptionality criteria detailed on page 2 above.
6. Workforce	<p>1.NHS primary care prescribers who prescribe GF food to patients with established gluten sensitive enteropathy (Coeliac disease) will have reduced administration of prescribing and repeat prescribing.</p> <p>2. Pharmacists who dispense prescriptions, and manufacturers who supply GF food to the NHS for prescribing will have reduced income from per-item prescription payments</p> <p>3. Primary care clinicians who currently prescribe GF products may receive complaints from patients if they are no longer able to prescribe it.</p> <p>4. Commissioners may receive complaints from</p>		<p>6 and 12 monthly assessment of prescribing spend / items issued for GF products will be undertaken by the ICB.</p> <p>There is an increasing need for enhanced community pharmacy services so lost income likely to be made up elsewhere e.g., through pharmacy first initiative.</p> <p>Clear public communications: explain why situation is different now: harmonisation and financial constraints.</p> <p>Clear public communications: learn from WY places who have already done this:</p> <ul style="list-style-type: none"> - Signposting patients to alternative products. Other dietary alternatives to gluten free food are available cheaply e.g., rice, potatoes for dietary staples. - Food banks: working with local foodbanks to promote donations of long life GF products. - Link in with community groups and the VCSEs. - Ensuring there is a collated system of information resources for patients. <p>Signposting and information: the ICB can produce/ commission information leaflets for patients and prescribers, outlining alternatives to branded GF products (including goods that are naturally GF) and to further information, e.g., from Coeliac UK</p> <p>Clear exceptionality criteria for primary care clinicians and prescribing clinicians, as detailed on page 2 above.</p>

	<p>the public for reversing a decision that was previously made in Calderdale and Leeds CCGs following consultation.</p>		
<p>7. Health inequalities</p>	<p>1. People who receive income related exemption from prescription charges will face additional costs of buying GF food.</p> <p>2. People who live in rural areas may have reduced access to affordable GF food products compared with those living in urban areas as these are more commonly available in larger supermarkets.</p> <p>3. People who care for adults or children could be impacted by the changes as they are often responsible for food choices and meal preparation for the patient.</p>		<ul style="list-style-type: none"> • Where WY places stopped the prescribing of GF products in 2016 and 2017, they asked foodbanks to include gluten free foods in their request for donations. • The proposed mitigations for Calderdale and Leeds are: <ul style="list-style-type: none"> - Signposting patients to alternative products. Other dietary alternatives to gluten free food are available cheaply e.g., rice, potatoes for dietary staples. - Food banks: working with local foodbanks to promote donations of long life GF products. - Link in with community groups and the VCSEs. - Guidance on best practice of annual reviews for coeliac patients as per NICE guidance to ensure we're managing patients who have specific medical conditions that could be impacted by the proposed change. - Places to share approach to mitigating actions. - Ensuring there is a collated system of information resources for patients. - Signposting and information: the ICB can produce/ commission information leaflets for patients and prescribers, outlining alternatives to branded GF

products (including goods that are naturally GF) and to further information, e.g., from Coeliac UK

GPs will be encouraged to carry out routine annual reviews, in accordance with NICE Guidance (National Institute for Health and Care Excellence) <https://www.nice.org.uk/guidance/ng20/chapter/Recommendations#monitoring-in-people-with-coeliac-disease> which will identify any health needs and will support coeliac patients.

On-line options for delivery are available for those patients who have limited mobility or can't buy GF products from their local shops, although buying GF products this way is likely to come with delivery charges. Leeds is primarily an urban area where there ought to be larger supermarkets where patients can buy GF products. Calderdale does have some rural areas so it will be a consideration for patients living in rural areas as to whether they are impacted by reduced access to GF products, and how the WY ICB can ensure mitigating actions address this.

Clinical staff in undertaking an evidenced based clinical review of a patient determines the patient has exceptional clinical circumstances, can prescribe GF products on prescription for the patient. That clinical review would be recorded on the patient's medical record.

Should clinicians identify a number of patients meeting clinical exceptionality criteria this most likely would give cause to review the existing policy or for, any future policy review to consider the exclusion of the affected group, such that they would be prescribed GF products.

Monitoring and review of the impact of the proposal will be via data that will inform where we have made changes and implemented mitigations to determine whether those mitigations addressed the negative impact of the change. Feedback from patients and primary care clinicians via surveys

			engagement activities will provide the qualitative data for said monitoring and review. The monitoring and review will be undertaken by the WY ICB Clinical and Professional Directorate where prescribing and medicines and clinical policy will sit from 1 April 2024.
8. Sustainability	<p>1.If GF products are no longer prescribed across NHS WY ICB, there will be recurrent financial savings of £222k, supporting financial sustainability.</p> <p>2. No impact on environmental sustainability identified.</p>		<p>6 and 12 monthly assessments of prescribing spend for GF products will be undertaken by the ICB.</p> <p>The cost of re-introducing provision of GF products in Bradford Districts and Craven, Kirklees and Wakefield is estimated to be £300k based on prescribing activity in Calderdale and Leeds.</p>
9. Other	<p>Reputational Impact on the WY ICB in stopping prescribing of GF Products at a time when people on low incomes and may be exempt from prescription charges would stop being prescribed GF Products and would have to find alternative dietary products and/or fund the purchase of GF Products themselves or turn to food banks for them or to the third</p>		<p>Adopting the proposal to withdraw the funding of GF products on prescription would affect around 900 people who are currently in receipt of GF products on prescription (725 people in Leeds, 205 people in Calderdale, approximately) as stated in the two involvement campaigns run in 2023.</p> <p><i>Of the 294 people who responded to the patient survey and answered the question: Do you or the person you care for pay for your prescriptions? 79 people answered Yes and 215 people answered No. Those people who don't pay for their prescription charges will be impacted more than those people who do pay for their prescription charges. Only 294 people responded to this question out of approximately 900 people who have been identified as being in receipt of GF prescriptions and had been sent the survey to complete via a letter, text or email with a link to the online survey (see page 14 of the involvement report above).</i></p> <p><u>Stage 1 – feedback from people directly affected</u></p>

sector/charities/community groups for support.

We received feedback from 300 patients who were in receipt of gluten free products on prescription. 294 patients completed the survey and 4 shared their views by email. 2 paper surveys arrived after the closing date; these were not included in the analysis but were reviewed to establish if the views raised were consistent with those that we had already received, which they were. Of those that completed the survey, 101 were from Calderdale and 193 were from Leeds.

89.4% (262) of all people that responded to the survey stated that the decision to stop prescribing gluten free products would have an impact on them or their household. The following themes were raised:

Views on the proposal

- People do not support the proposal and want gluten-free products to continue to be prescribed.
- Many people mentioned that eating gluten-free food is not a lifestyle choice and people with coeliac disease must eat gluten-free food to stay healthy. There was a feeling from some people that they should receive the same level of support as other conditions e.g., type 1 diabetics are not expected to pay for their insulin.
- Some people mentioned how the number of items available on prescription had already been reduced to just bread and flour.
- A few people mentioned that they didn't realise that they could receive gluten-free products on prescription.

Cost and availability of gluten-free products in supermarkets

- Many people commented on the high cost of gluten-free products in supermarkets, with the view that items were significantly more expensive than an equivalent product containing gluten.
- There was real concern as to the impact on people on low incomes especially during the current cost of living crisis, and those families where more than one person had been diagnosed as coeliac.
- It was felt that products available in supermarkets were not comparable to the products available on prescription. Mention was made to Juvella and Glutafin, which contain replacement vitamins and minerals that may be required by coeliac patients to help maintain a healthy diet. Many also felt that the products available on prescription were of a higher quality and tasted better. Some mentioned the difficulty of obtaining gluten-free products and how they would have to travel further to buy food from the larger supermarkets as their local shop, Aldi and Lidl did not sell gluten-free products.
- Impact on diet
- A few people were concerned that if products were no longer available on prescription it could lead to them not adhering to their diet, due to the financial cost of purchasing from supermarkets. This could lead to serious health conditions developing which in turn would cost the NHS significantly more than prescribing gluten-free products.
- Some people mentioned the negative impact it would have on their diet as they would no longer be able to afford to eat bread.
- A few parents talked about how their children currently use the prescription bread to enable them to take sandwiches to school and expressed their concerns about the negative impact this would have on their children if they were no longer able to do this.

Most people raised cost as the most significant impact. There was an understanding that we must have consistent policies across West Yorkshire and that the NHS in West Yorkshire needs to make the best use of its limited resources. However, most respondents do not want gluten-free prescribing in Calderdale and Leeds to be stopped. Many respondents stated that coeliac is a disease, not a choice and people living with coeliac disease must follow a gluten-free diet. This would be difficult without having gluten-free products on prescription mainly due to the cost.

Stage 2 – wider public involvement

The key themes from this involvement exercise relevant to GF prescribing were:

- Availability and quality of gluten-free products. For example:
 - one respondent explained that it was extremely difficult to get Juvella bread other than on prescription.
 - one respondent said that the bread provided on prescription is much better quality than that bought from the shops.
 - difficulty accessing GF bread and flour in rural or poorer areas.
- Cost of gluten-free products and impact on lower incomes. The common theme was the higher cost of GF bread compared to regular breads.
- Agreement with the recommendation and that the NHS needs to make the best use of limited resources.
- Suggestions e.g., making GF Products available for children, replacing the prescription with a direct payment.

Of the 86 respondents to the stage 2 survey, 83 shared their views on the recommendation for gluten-free prescribing: -

Availability and quality of GF products = 20

Cost of GF products and impact on lower incomes = 74

Agree with the recommendation and that the NHS must make best use of limited resources = 10

Suggest a mitigation = 7

There has been threat of legal challenge to the WY ICB's Transformation Committee's decision made on 31 October 2023 to stop the prescribing of GF Products in both Calderdale and Leeds.

Prescribing of GF Products was stopped in Bradford District and Craven in 2016, and in both Kirklees and Wakefield in 2017. This has created a disparity across the WY ICB with having different patient access thresholds for Calderdale and Leeds for Coeliac patients with the formation of the WY ICB on 1 July 2022. The WY ICB is required to address this inequity of access for the people of WY. It has an action plan to mitigate the impact on patients in Calderdale and Leeds who are currently prescribed GF products to manage its proposal to stop the prescribing of GF Products in those two places, with primary care colleagues carrying annual reviews of Coeliac patients in line with NICE Guidance and prescribing clinicians who consider a patient meets the exceptionality criteria will still be able to prescribe GF products for that patient. The support and access to information for patients affected by this proposed change are detailed below, with specific mitigating actions for WY ICB colleagues in Calderdale and in Leeds:

- The proposed mitigations for Calderdale and Leeds are:

- Signposting patients to alternative products. Other dietary alternatives to gluten free food are available cheaply e.g., rice, potatoes for dietary staples.

- Food banks: working with local foodbanks to promote donations of long life GF products. - Link in with community groups and the VCSEs.

- Ensuring there is a collated system of information resources for patients.

- Signposting and information: the ICB can produce/ commission information leaflets for patients and prescribers, outlining alternatives to branded GF products (including goods that are naturally GF) and to further information, e.g., from Coeliac UK.

- On-line options for delivery are available for those patients who have limited mobility or can't buy GF products from their local shops, although buying GF products this way is likely to come with delivery charges. Leeds is primarily an urban area where there ought to be larger supermarkets where patients can buy GF products. Calderdale does have some rural areas so it will be a consideration for patients living in rural areas as to whether they are impacted by reduced access to GF products, and how the WY ICB can ensure mitigating actions address this.

Additional mitigating actions are proposed by the WY ICB:

The dietician who wrote to the WY ICB about its proposal to stop prescribing GF products in Calderdale and Leeds, is keen to support coeliac patients across WY and is setting up a working group with dieticians from other places to see how we can provide information and guidance for coeliac patients across WY. One suggestion is to roll out the Bradford Coeliac Disease Newsletter across WY. This work is ongoing.

Monitoring and review of the impact of the proposal will be via data that will inform where we have made changes and implemented mitigations to determine whether those mitigations addressed the negative impact of the change. Feedback from patients and primary care clinicians via surveys and engagement activities will provide the qualitative data for said monitoring and

			review. The monitoring and review will be undertaken by the WY ICB Clinical and Professional Directorate where prescribing and medicines and clinical policy will sit from 1 April 2024.
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H. Action Plan				
Describe the action that will be taken to mitigate negative impacts				
Identified impact	What action will you take to mitigate the impact?	How will you measure impact / monitor progress (Include all identified positive and negative impacts. Measurement may be an existing or new quality indicator / KPI)	Timescale (When will mitigating action be completed?)	Lead (Person responsible for implementing mitigating action.)
Difficulty for people obtaining gluten free food / alternative products	<p>Signposting and information: produce information leaflets for patients and prescribers, outlining alternatives to branded GF products (including goods that are naturally GF) and to further information, e.g., from Coeliac UK.</p> <ul style="list-style-type: none"> • Where WY places stopped the prescribing of GF products in 2016 and 2017, they asked foodbanks to include gluten free foods in their request for donations. 	<p>Feedback from patients and clinicians to ICB.</p> <p>Clinical staff in undertaking an evidenced based clinical review of a patient determines the patient has exceptional clinical circumstances, can prescribe GF products on prescription for the patient. That clinical review would be recorded on the patient's medical record.</p> <p>Should clinicians identify a number of patients meeting</p>	<p>Signposting and links to resources: Immediate.</p> <p>Establish working relationships with WY VCSEs and community groups, if not done so already, and connect with food banks to increase and widen the provision of GF products for people who access foodbanks. Also, to provide support for Coeliac patients around education</p>	<p>Combination of WY ICB colleagues: Clinical Policy and IFR function, Pharmacy and Medicine Optimisation Leads, Place planned care and medicines leads, Primary care leads and GP Leads.</p> <p>Dr James Thomas, WY ICB Medical Director and Directors and Associate Directors of the WY ICB, and programme leads.</p>

	<ul style="list-style-type: none"> • The proposed mitigations for Calderdale and Leeds are: - Signposting patients to alternative products. Other dietary alternatives to gluten free food are available cheaply e.g., rice, potatoes for dietary staples. - Food banks: working with local foodbanks to promote donations of long life GF products. - Link in with community groups and the VCSEs. <p>On-line options for delivery are available for those patients who have limited mobility or can't buy GF products from their local shops, although buying GF products this way is likely to come with delivery charges. Leeds is primarily an urban area where there ought to be larger supermarkets where patients can buy GF products. Calderdale does have some rural areas so it will be a consideration for patients living in rural areas as to</p>	<p>clinical exceptionality criteria this most likely would give cause to review the existing policy or for, any future policy review to consider the exclusion of the affected group, such that they would be prescribed GF products.</p>	<p>and support in accessing alternative GF products.</p> <p>Conversations to be had with local councils about the provision of GF products for school children who may or may not qualify for free school meals with priority for children who qualify for free school meals.</p> <p>Training for WY ICB staff managing the public telephone number and email address inbox as to where to signpost patients or members of public enquiring about GF products and support for. Consider a dedicated webpage on ICB website for patients and public to access with information resources.</p>	
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	whether they are impacted by reduced access to GF products, and how the WY ICB can ensure mitigating actions address this.			
Complaints from public and professionals	<p>Clear public communications: explain why situation is different now: harmonisation / finance / cost of living crisis.</p> <p>Clear public communications: learn from WY places who have already done this.</p>	Feedback from patients and clinicians to ICB.	Communications prepared for response. Update ICB and partnership website following decision as a matter of urgent priority.	Karen Coleman (Associate Director – Communications). WY ICB Complaints and Corporate Governance Function – Laura Ellis, Corporate Governance Director
Recurrent financial savings and addressing disparity of patient access thresholds across West Yorkshire Places	<p>Harmonisation of commissioning policy patient access threshold.</p> <p>Monitoring how many patients meet exceptionality criteria to be prescribed GF products.</p> <p>Working with primary care and secondary care clinicians in reviewing implementation of harmonised patient access threshold and the need to review this.</p>	Regular monitoring of prescribing spend and outcomes from monitoring and review of proposal and mitigating actions to address the impact on people adversely affected by the change.	Ongoing and as a matter of priority within 6 months of implementing the proposal/change.	<p>Combination of WY ICB colleagues: Clinical Policy and IFR function, Pharmacy and Medicine Optimisation Leads, Place planned care and medicines leads, Primary care leads and GP Leads.</p> <p>Dr James Thomas, WY ICB Medical Director and Directors and Associate Directors of the WY ICB, and programme leads.</p>
Please see the EIA for the action plan to manage equality				

and equity of access impacts.				
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I. Monitoring & review; Implementation of action plan and proposal			
<p>The action plan should be monitored regularly to ensure a) actions required to mitigate negative impacts are undertaken and b) KPIs / quality indicators are measured in a timely manner so positive and negative impacts can be evaluated during implementation / the period of service delivery.</p> <p>Outcome: Once the proposal has been implemented, the <u>actual</u> impacts will need to be evaluated and a judgement made as to whether the intended outcomes of the proposal were achieved</p>			
Implementation: State who will monitor / review:	Name of individual, group or committee	Role	Frequency
a) that actions to mitigate negative impacts have been taken	Combination of WY ICB colleagues: Clinical Policy and IFR function, Pharmacy and Medicine Optimisation Leads, Place planned care and medicines leads, Primary care leads and GP Leads.	Director level, Project Managers, Programme Support, Pharmacists, GPs, and primary care staff.	3 monthly to 6 monthly during year one, and 6 monthly thereafter.
b) the quality indicators during the period of service delivery State the frequency of monitoring (e.g. Recovery Group Monthly, QSC Quarterly, J. Bloggs, Project Manager Unplanned Care Monthly	a) Combination of WY ICB colleagues: Clinical Policy and IFR function, Pharmacy and Medicine Optimisation Leads, Place planned care and medicines leads, Primary care leads and GP Leads.	Director level, Project Managers, Programme Support, Pharmacists, GPs, and primary care staff.	3 monthly to 6 monthly during year one, and 6 monthly thereafter.

	b) Corporate Governance (Complaints) and Clinical Policy & IFR function teams		
Outcome	Name of individual, group or committee	Role	Date
Who will review the proposal once the change has been implemented to determine what the actual impacts were?	WY ICB Medical Director, Dr James Thomas, Clinical and Professional Directorate, WY ICB	WY ICB Medical Director	3 monthly to 6 monthly during year one, and 6 monthly thereafter up to 3 years maximum as Clinical Policy is reviewed every 3 years unless there is revised guidance or policy direction from NHS England before this date.

J. Summary of the QEIA

Provide a brief summary of the results of the QEIA, e.g., highlight positive and negative potential impacts; indicate if any impacts can be mitigated; taking this into account, state what the overall expected impact will be of the proposed change.

The QEIA and summary statement must be reviewed by a member of the Quality Team and include next steps

Positive Impacts:

- Disparity between WY Places in the prescribing of GF Products will be addressed. There currently exists different patient access thresholds for GF Products in Calderdale and Leeds, with the prescribing of GF Products stopped in Bradford District and Craven in 2016, and in both Kirklees and Wakefield in 2017. This presents an inequity of access and variation of care for people living in those WY places where prescribing of GF Products was stopped some years ago.
- Consistency in applying exceptional clinical criteria for those patients who meet the access threshold to be prescribed GF products. This criteria will apply to all patients living in West Yorkshire **as detailed on page 2 above**.
- GPs and Primary Care Colleagues will be encouraged to carry out annual reviews of Coeliac patients as per NICE Guidance to support them manage their health condition. WY ICB colleagues will provide support to adopt this clinical best practice where it is currently not implemented.
- Support and education to be provided to patients in Calderdale and Leeds to manage the change and impact on them, with that being widened to all people across WY who have Coeliac disease and for the carers and family members of people with Coeliac disease in the form of:

- - Signposting patients to alternative products. Other dietary alternatives to gluten free food are available cheaply e.g., rice, potatoes for dietary staples.
- - Ensuring there is a collated system of information resources for patients.
- - Signposting and information: the ICB can produce/ commission information leaflets for patients and prescribers, outlining alternatives to branded GF products (including goods that are naturally GF) and to further information, e.g., from Coeliac UK
- - Produce WY ICB information leaflets and other information resources such as websites, digital Apps, third sector organisations, Posters.
- - Consider a dedicated webpage on ICB website for patients and public to access with information resources.

Experience of Care: People in WY will see other services better maintained / new medicines and services available due to the financial resources released by stopping prescribing of GF products.

Workforce: NHS primary care prescribers who prescribe GF food to patients with established gluten sensitive enteropathy (Coeliac disease) will have reduced administration of prescribing and repeat prescribing.

Sustainability: If GF products are no longer prescribed across NHS WY ICB, there will be recurrent financial savings of £222k, supporting financial sustainability.

Proactive action by the WY ICB and Place Colleagues in undertaking the following to implement mitigating actions:-

- Food banks: working with local foodbanks to promote donations of long life GF products. - Link in with community groups and the VCSEs to identify and secure support for people impacted by the change.
- On-line options for delivery are available for those patients who have limited mobility or can't buy GF products from their local shops, although buying GF products this way is likely to come with delivery charges. Leeds is primarily an urban area where there ought to be larger supermarkets where patients can buy GF products. Calderdale does have some rural areas so it will be a consideration for patients living in rural areas as to whether they are impacted by reduced access to GF products, and how the WY ICB can ensure mitigating actions address this.

Additional mitigating actions are proposed by the WY ICB: The dietician who wrote to the WY ICB about its proposal to stop prescribing GF products in Calderdale and Leeds, is keen to support coeliac patients across WY and is setting up a working group with dieticians from other places to see how we can provide information and guidance for coeliac patients across WY. One suggestion is to roll out the Bradford Coeliac Disease Newsletter across WY. This work is ongoing.

Monitoring and review of the impact of the proposal will be via data that will inform where we have made changes and implemented mitigations to determine whether those mitigations addressed the negative impact of the change. Feedback from patients and primary care clinicians via surveys

and engagement activities will provide the qualitative data for said monitoring and review. The monitoring and review will be undertaken by the WY ICB Clinical and Professional Directorate where prescribing and medicines and clinical policy will sit from 1 April 2024.

Negative impacts: Patient Safety: 1. Some GF foods are more expensive than everyday brands. If people turn to cheaper gluten-containing products, they may suffer health complications. 2. Some people with complex co-morbidities such as complex allergy may struggle to maintain adequate dietary intake for health. If they are unable to afford suitable gluten free products other health conditions may also deteriorate.

Experience of Care: People in Leeds and Calderdale will no longer be able to access Gluten Free products on prescription, which they have previously been able to access. This would be against the wishes of people in Leeds and Calderdale expressed in WY ICB consultations.

Clinical Effectiveness: Some GF bread and flour mixes are more expensive than everyday brands. If people turn to cheaper gluten-containing products they may suffer health complications and not be able to manage their coeliac disease effectively through diet.

Equality – addressed in the EIA: See full details in said document.

Workforce: 1. Pharmacists who dispense prescriptions, and manufacturers who supply GF food to the NHS for prescribing will have reduced income from per-item prescription payments. 2. Primary care clinicians who currently prescribe GF products may receive complaints from patients if they are no longer able to prescribe it. 3. Commissioners may receive complaints from the public for reversing a decision that was previously made in Calderdale and Leeds CCGs following consultation.

Mitigation: 6 and 12 monthly assessment of prescribing spend / items issued for GF products will be undertaken by the ICB up to a maximum of 3 years.

Reputational: Reputational Impact on the WY ICB in stopping prescribing of GF Products at a time when people on low incomes and may be exempt from prescription charges would stop being prescribed GF Products and would have to find alternative dietary products and/or fund the purchase of GF Products themselves or turn to food banks for them or to the third sector/charities/community groups for support.

There has been threat of legal challenge to the WY ICB's Transformation Committee's decision made on 31 October 2023 to stop the prescribing of GF Products in both Calderdale and Leeds.

EXTENSIVE MITIGATING ACTIONS TO ADDRESS THE IMPACT OF THE CHANGE ON PATIENTS IN CALDERDALE AND LEEDS ARE DETAILED ABOVE WITH A MECHANISM TO MEASURE THE SUCCESS (OR NOT) OF THOSE MITIGATING ACTIONS.

K: Review (to be completed following implementation)		
Insert Details		
1.Review completed by	WY ICB EDI Lead – Ali Bishop and Catherine Borrill	
2.Date of Review	6 months from implementation	
3.Scheme start date	To be confirmed	
L. Quality and Equality Team review undertaken (by respective population lead)		
Name	Role	Date

M. For Quality Team use only (for panel)	
Reference	IA/
Form completed by	Names and roles
Date reviewed by quality team	
List for panel	Y/N
Next Panel date	
Recommendations & feedback from quality lead	

N: Likely financial impact of the change (and/or level of risk to the ICB) (as advised by finance lead)				
Low	X	Medium		High

Approval to proceed	Name/ Role	Y/N	Date
Quality Lead			
Date returned to PMO	State name and date		
Proposed 6-month review date (post implementation)	To be agreed with Pathway Integration/Programme or scheme lead – WY ICB Clinical and Professional Directorate, Dr James Thomas		

Appendix A: Impact Matrix

This matrix is included to help your thinking and determine the level of impact on each area.

Likelihood		
0	Not applicable	
1	Rare	Not expected to occur for years. Will occur in exceptional
2	Unlikely	Expected to occur at least annually. Unlikely to occur.
3	Possible	Expected to occur at least monthly. Reasonable chance of
4	Likely	Expected to occur at least weekly. Likely to occur.
5	Almost Certain	Expected to occur at least daily. More likely to occur than not.

		Opportunity						Consequence				
Likelihood		5	4	3	2	1	0	-1	-2	-3	-4	-5
	5	25	20	15	10	5	0	-5	-10	-15	-20	-25
	4	20	16	12	8	4	0	-4	-8	-12	-16	-20
	3	15	12	9	6	3	0	-3	-6	-9	-12	-15
	2	10	8	6	4	2	0	-2	-4	-6	-8	-10
	1	5	4	3	2	1	0	-1	-2	-3	-4	-5

Category	
	Opportunity
	Low - Moderate Risk
	High Risk

Opportunity and Consequence			
Impact	Score		The proposed change is anticipated to lead to the following level of opportunity and/or consequence:
Positive	5	Excellence	Multiple enhanced benefits including excellent improvement in access, experience and/or outcomes for all patients, families and carers. Outstanding reduction in health inequalities by narrowing the gap in access, experience and/or outcomes between people with protected characteristics and the general population. Leading to consistently improved standards of experience and an enhancement of public confidence, significant improvements to performance and an improved and sustainable workforce.
	4	Major	Major benefit leading to long term improvements and access, experience and /or outcomes for people with this protected characteristic. Major reduction in health inequalities by narrowing the gap in access, experience and /or outcomes between people with this protected characteristic and the general population. Benefits include improvements in management of patients with long term effects and compliance with national standards.
	3	Moderate	Moderate benefits requiring professional intervention with moderate improvement in access, experience and /or outcomes for people with this protected characteristic. Moderate reduction in health inequalities by narrowing the gap in access, experience and /or outcomes between people with this protected characteristic and the general population.
	2	Minor	Minor improvement in access, experience and /or outcomes for people with this protected characteristic. Minor reduction in health inequalities by narrowing the gap in access, experience and /or outcomes between people with this protected characteristic and the general population.
	1	Negligible	Minimal benefit requiring no/minimal intervention or treatment. Negligible improvement in access, experience and /or outcomes for people with this protected characteristic. Negligible reduction in health inequalities by narrowing the gap in access, experience and /or outcomes between people with this protected characteristic and the general population.
Neutral	0	Neutral	No effect either positive or negative
Negative	-1	Negligible	Negligible negative impact on access, experience and /or outcomes for people with this protected characteristic. Negligible increase in health inequalities by widening the gap in access, experience and /or outcomes between people with this protected characteristic and the general population. Potential to result in minimal injury requiring no/minimal intervention or treatment, peripheral element of treatment suboptimal and/or informal complaint/inquiry
	-2	Minor	Minor negative impact on access, experience and /or outcomes for people with this protected characteristic. Minor increase in health inequalities by widening the gap in access, experience and /or outcomes between people with this protected characteristic and the general population. Potential to result in minor injury or illness, requiring minor intervention and overall treatment suboptimal
	-3	Moderate	Moderate negative impact on access, experience and /or outcomes for people with this protected characteristic. Moderate increase in health inequalities by widening the gap in access, experience and /or outcomes between people with this protected characteristic and the general population. Potential to result in moderate injury requiring professional intervention.
	-4	Major	Major negative impact on access, experience and /or outcomes for people with this protected characteristic. Major increase in health inequalities by widening the gap in access, experience and /or outcomes between people with this protected characteristic and the general population. Potential to lead to major injury leading to long-term incapacity/disability
	-5	Catastrophic	Catastrophic negative impact on access, experience and /or outcomes for people with this protected characteristic. Catastrophic increase in health inequalities by widening the gap in access, experience and /or outcomes between people with this protected characteristic and the general population. Potential to result in incident leading to death, multiple permanent injuries or irreversible health effects, an event which impacts on a large number of patients, totally unacceptable level or effectiveness of treatment, gross failure of experience and does not meet required standards

Appendix B: Guidance notes on completing the impacts section G

Domain	Consider.....
<p>1. Patient Safety</p>	<ul style="list-style-type: none"> • Safe environment • Preventable harm • Reliability of safety systems • Systems & processes to prevent healthcare acquired infection • Clinical workforce capability and appropriate training and skills • Provider's meeting CQC Essential Standards
<p>2. Experience of care</p>	<ul style="list-style-type: none"> • Respect for person-centred values, preferences, and expressed needs, including cultural issues; the dignity, privacy and independence of service users; quality-of-life issues; and shared decision making; • Coordination and integration of care across the health and social care system; • Information, communication, and education on clinical status, progress, prognosis, and processes of care in order to facilitate autonomy, self-care and health promotion; • Physical comfort including pain management, help with activities of daily living, and clean and comfortable surroundings; • Emotional support and alleviation of fear and anxiety about such issues as clinical status, prognosis, and the impact of illness on patients, their families and their finances; • Use co-production with the population and service users as the default position for project design. • Use what we know from insight and feedback in project design and be explicit in the expected outcomes for experience of care improvements. • Involvement of family and friends, on whom patients and service users rely, in decision-making and demonstrating awareness and accommodation of their needs as caregivers; • Transition and continuity as regards information that will help patients care for themselves away from a clinical setting, and coordination, planning, and support to ease transitions; • Access to care e.g., time spent waiting for admission, time between admission and placement in an in-patient setting, waiting time for an appointment or visit in the out-patient, primary care or social care setting. <p>[Adapted from the NHS Patient Experience Framework, DoH 2011] revised in: NHS Patient Experience Improvement Framework 2018</p>
<p>3. Clinical Effectiveness</p>	<ul style="list-style-type: none"> • Implementation of evidence based practice (NICE, pathways, royal colleges etc.) • Clinical leadership • Care delivered in most clinically and cost effective setting • Variations in care • The quality of information collected and the systems for monitoring clinical quality • Locally agreed care pathways • Clinical engagement • Elimination of inefficiency and waste

	<ul style="list-style-type: none"> • Service innovation • Reliability and responsiveness • Accelerating adoption and diffusion of innovation and care pathway improvement • Preventing people dying prematurely • Enhancing quality of life • Helping people recover from episodes of ill health or following injury
4. Equality	<ul style="list-style-type: none"> • In order to answer section C and G4 the groups that need consideration are; • Protected characteristics; age, disability, gender reassignment, pregnancy and maternity, race, religion or belief, sex, sexual orientation (Use the hyperlinks for further information) • Other groups would include, but not be limited to, people who are; carers, homeless, living in poverty, asylum seekers / refugees, in stigmatised occupations (e.g. sex workers), problem substance use, geographically isolated (e.g. rural) and surviving abuse
5. Safeguarding	<ul style="list-style-type: none"> • Will this impact on the duty to safeguard children, young people and adults at risk? • Will this have an impact on Human Rights – for example any increased restrictions on their liberty?
6. Workforce	<ul style="list-style-type: none"> • Staffing levels • Morale • Workload • Sustainability of service due to workforce changes (Attach key documents where appropriate)
7. Health Inequalities	What guidance can we use here?
8. Sustainability	<p>See Climate-change-and-sustainability-paper-october-2020.pdf Climate change poses a major threat to our health as well as our planet. The environment is changing, that change is accelerating, and this has direct and immediate consequences for our patients, the public and the NHS.</p> <p>Also consider; technology, pharmaceuticals, transport, supply/purchasing, waste, building/sites and impact of carbon emissions</p> <p>Visit; Greener NHS for more info</p>
9. Other	<ul style="list-style-type: none"> • Publicity/reputation • Percentage over/under performance against existing budget • Finance including claims