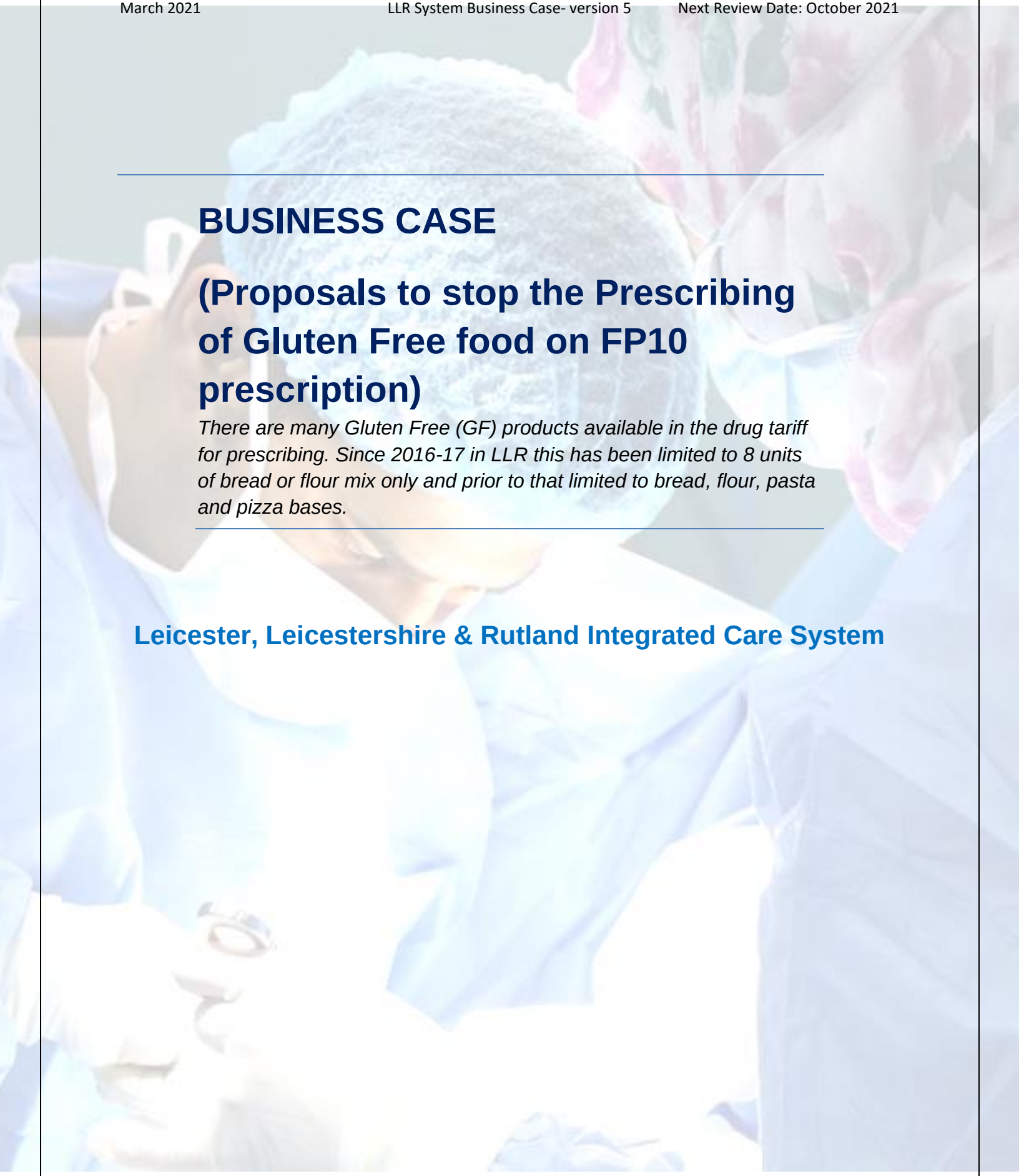

BUSINESS CASE

(Proposals to stop the Prescribing of Gluten Free food on FP10 prescription)

There are many Gluten Free (GF) products available in the drug tariff for prescribing. Since 2016-17 in LLR this has been limited to 8 units of bread or flour mix only and prior to that limited to bread, flour, pasta and pizza bases.

Leicester, Leicestershire & Rutland Integrated Care System

Checklist organisation

Please complete, as appropriate.

Author of the Business Case (Group and organisation)	**(previously completed by Lesley Gant on behalf of IMODG), updated by Anne-Marie Harrison, Hamza Ismail, Susan Venables.**
Name of the partner organisation(s) that will deliver the project	NA
Lead organisation (LPT, UHL or CCG).	ICB
Has the Business Case been presented and approved at local organisation? If so, give details. (which groups/ date of meetings, was this for information, assurance or authority to proceed?	Previously reported to IMODG.
Has the Business Case been presented and approved at the Sponsor organisation? If so, give details.	NA

Has the Business Case been recommended for approval by the System Transformation Steering Group?	

Authority	Name & Signature	Date of sign-off	Comments
Authorised signatory on behalf of Clinical Executive (name and e-signature)	Dr Nilesh Sanganee		
Authorised signatory on behalf of Sponsor organisation (name and e-signature)			
Authorised signatory on behalf of System Transformation Steering Group (name and e-signature)			
Authorised signatory on behalf of System Operational Group (SOG) (name and e-signature)			

Contents

SECTION 1: BUSINESS CASE GUIDANCE SHEET

Executive Summary

This section should be a brief, succinct paragraph summarising the whole business case and include the pertinent information the reader would need to allow them to understand the purpose and ask that you are putting forward.

Case for Change

Reasons for project – It should outline what the problem is, why the problem should be solved and why this project is needed to solve the problem.

Business options - Show how the preferred option will meet the reasons for the project and why the other options were discarded, including a 'Do Nothing' option as a contrast. On completing the comparison grid it should be clear why there is a 'Preferred Option'.

Expected benefits - The 'payback; these should be quantifiable, although we can put tolerances on them. Finances can be financial and/or qualitative

Expected dis-benefits - anything perceived by the stakeholder as having negative consequences. Don't have to be measurable, but must be a fact (not a risk) and must indicate a negative connotation

Timescales - How long the project will take (plus dates, if possible), how long to get the benefits, when benefits should occur

Evidence base

Has it been done elsewhere and is there data to support it or has it been done by the project team in the form of a pilot study?

Strategy

How does the project align to the LLR Quintuple Aims and the Ten System Expectations?

Finances

The finances section needs to be completed in collaboration with a Finance Business Partner and this will need to be evidenced in order to ensure that the finances have been worked up accurately and correctly. Ensure your methodology is clear and comprehensible. The accompanying excel document, when completed, will provide the tables included within this template. Please submit the full working excel file along with the business case.

Impact Assessments

Please ensure the separate impact assessment documents are completed and signed off by the Quality Team/Chief Nurse. Business Cases will not be signed off without full impact assessments being conducted.

Scope, Assumptions and Dependencies

What is included (in scope), what is excluded (out of scope) and what does the project depend on (e.g. delivery of another project, implementation of IT system, provision of investment, recruitment of key staff etc.).

Information Technology

For this section, please consider what are the IT requirements for the project, who are the IT stakeholders, what data will be generated, how will it be managed, IT costs etc.

Project Planning

Your milestones will be high level, they should include start and end dates and they should be underpinned by deliverables in your project plan.

A risk is something that potentially will happen, whilst an issue actually is occurring and needs to be managed. Please consult the risk matrix for scoring.

There are two tables for KPIs and System-Aligned Outcome Measures. KPIs may be nationally mandated, or locally created, whereas the outcome measures are agreed at system-level

SECTION 2: OUTLINE BUSINESS CASE

Project/Programme title:	Stopping the prescribing of Gluten free foods on FP10 prescriptions
Sponsor organisation	LLR ICB
Project manager:	**Anne-Marie Harrison, Hamza Ismail and Joanne Ryder**
Clinical lead:	**Claire Elwood**
Senior Responsible Officer (SRO):	Dr Nilesh Sanganee
Business Case completion date:	21.07.21 and 15/03/24
Project start and expected end date:	End and completion date dependent on public consultation and notice period for stopping.
Partners involved:	
Investment required	
Financial benefit: **When and how much?**	Releases efficiencies as there is a safe non prescription option. The annual spend 2022-23 £259,832, If approved the saving will be annual spend or pro rata for the remainder of the year
Quality and other benefits	More areas across the East Midlands are moving towards or have already removed gluten free food provision from FP10 prescriptions. Historically, availability of gluten free foods was limited, therefore obtaining these products from community pharmacies via prescriptions improved access to them. With the increased awareness of coeliac disease and gluten sensitivity as well as a

	general trend towards eating less gluten, these products are now much more widely available than before. Many major supermarkets and other retailers now commonly stock gluten free foods as well as other special diet alternatives both online and in-store. Furthermore, improved food labelling now means people are able to see whether ordinary food products are free from gluten and can be safely eaten. The price paid by the NHS for gluten free foods on prescription is much higher than the supermarket prices available to the public. Stopping prescribing of Gluten free food will realise prescribing savings in the region of £250K per year based on current rates of GF prescribing.

SECTION 3: EXECUTIVE SUMMARY

Why are you doing the project?	In 2016-2017 a review of Gluten free prescribing policy was consulted on with two options. Option 1 stop all GF prescribing or option 2 allow up to 8 units each month of Bread or flour mix only. Option 2 was agreed as the outcome. In Nov 2018 NHSE Primary Care Guidance was published following a national consultation. **The guidance states ICBs can restrict further by selecting bread only, mixes only or can choose to end prescribing of all GF foods if they feel this is appropriate for their population, whilst taking account of their legal duties to advance equality and have regard to reducing health inequalities.** More areas across the East Midlands are moving towards or have already removed gluten free food provision from FP10 prescriptions. According to Coeliac UK "Around 60% of all policy areas in England offer gluten free prescribing in line with the DHSC decision to retain bread and flour mix in 2017. Wales, Scotland and Northern Ireland prescribe gluten free staples in line with national prescribing guidelines."

	Historically, availability of gluten free foods was limited, therefore obtaining these products from community pharmacies via prescriptions improved access to them. With the increased awareness of coeliac disease and gluten sensitivity as well as a general trend towards eating less gluten, these products are now much more widely available than before. All major supermarkets and many other retailers now commonly stock gluten free foods as well as other special diet alternatives both online and in-store. Furthermore, improved food labelling now means people are able to see whether ordinary food products are free from gluten and can be safely eaten. The price paid by the NHS for gluten free foods on prescription is much higher than the supermarket prices available to the public. **We acknowledge that gluten free food products are often more expensive than their gluten containing equivalents. However, It is possible to eat a gluten free diet that follows the Eatwell Guide model for balanced eating without the need for any specialist dietary foods, simply by choosing naturally gluten free carbohydrate containing foods (e.g. rice and potatoes) as part of a healthy balanced diet.** The main aim and objective is to undertake a public consultation process to understand the impact of a decision to stop GF prescribing on the NHS across LLR ICB.
What are you doing?	Stop the prescribing of Gluten Free (GF) foods on FP10 completely.

How will it be delivered?	Following due process:
	• Approval of proposal and case for change by ICB
	• Approval of approach to public consultation by ICB.
	• Through a public consultation. The public consultation would:
	• Inform people about how the proposals have been developed.
	  ○ To work with key organisations e.g. Coeliac UK to reach those people who may be impacted by the proposals.
	  ○ Describe and explain the proposals for stopping gluten free products on NHS prescription.

	○ Consult people currently using gluten free products on prescription to understand their lived experience and what the proposals mean to them ○ To seek people's views, and understand the impact of the proposals on them ○ To ensure that a range of voices are heard which reflect the socio-demographics of the area, particularly the most vulnerable and those with protected characteristics. ○ To understand the responses made in reply to the proposals and take them into account in the final decision-making. ○ To respond to the feedback received ○ To ensure that the public consultation process complies with our legal requirements and duties. • Post consultation, the insights collected will be evaluated and analysed and a Report of Findings produced. • This Report of Finding would influence the final decision made in regards to Gluten Free Prescribing. • Final decision of ICB Board • Communications to all stakeholders
When will it start and when will it finish?	A 6 week public consultation is recommended. A six week period, both prior and post public consultation is needed to prepare for public consultation and deliver the Report of Findings. Public consultation will need to align with the schedule for Joint Health Overview and Scrutiny. Considerations needs to be given to new guidance issues in regards of ministerial powers to intervene in NHS reconfiguration introduced in 2024.
When are benefits expected to be delivered?	Dependent on the outcome of the public consultation, if the decision is made to stop prescribing the financial benefits to the ICB will be seen as soon as gluten free prescribing stops. However, the timescale will depend on the results

	of the consultation process and responses received particularly with regards to communication and support required for the affected patient cohort.
How long will mobilisation take?	The mobilisation will be guided by the outcome of the consultation and responses received particularly with regards to communication and support required for the affected patient cohort.
What are your local assurance mechanisms?	Liaison with Clinical Teams across LLR Liaison with Coeliac UK Liaison with Healthwatch Leicester and Leicestershire and Healthwatch Rutland

SECTION 4: CASE FOR CHANGE

Reasons for the project:	The ICB has a legal duty to seek to achieve system financial balance, and there is enormous pressure to deliver significant prescribing efficiencies to enable delivery of system priorities and the health prevention program. Region (NHS Midlands and East) have identified GF prescribing as an area where LLR ICB can make prescribing savings. LLR ICB are significantly above the England median across other ICB in cost/1,000 patients for GF prescribing. Since the last review there has been number of ICBs who have completely stopped prescribing gluten free products on the NHS, including the neighbouring ICBs (Nottinghamshire, Northamptonshire and Derbyshire). Within the midland's region LLR and Lincolnshire ICBs are the only organisations that have continued to prescribe GF products. If no gluten free products had been prescribed in LLR ICB for the financial year 2022-23, savings of £259K could have been realised. .
Expected Benefits	ICBs that restricted supply of gluten free foods generally did so on the grounds that commissioners are required to use public money to achieve the maximum health benefit.
Expected Dis-benefits	Patient representative groups, Coliac UK and some clinical teams oppose decision.

SECTION 4.1: BUSINESS OPTIONS:

Reference to:	Option 1 – Do nothing	Option 2	Option 3
Description of options:	Retain the existing agreement and formulary	Review current formulary - reviewing products and units. Scope what other areas have done	To cease prescribing of Gluten Free products across LLR
Key Benefits			
1	Patient not impacted - Prescription continue for patient for bread or mixes	Not all patients impacted - Prescription to continue for patient for either bread or mixes or both	Releases efficiencies and promotes self-care agenda
2		Some savings could be made by reviewing current products on formulary and review the units available to be prescribed.	Encourages a naturally balanced GF diet or the provision of GF foods in normal grocery shopping
3			
Summary (Select discounted or preferred against the appropriate option)	Discounted	Discounted	preferred

Preferred Option	
Briefly summarise why this is the preferred option.	Option 3 will produce prescribing savings in the region of £250K per year based on current rates of GF prescribing. A 5% efficiency target has been set for 2024-25 which is approximately £10 million.

	Stopping prescribing of GF foods will form part of the 2024-25 efficiency plan. Costs could increase with Option 1 and there would be no prescribing savings. Option 2 does not go far enough to achieve any significant savings. Option 2 may still receive challenges from patient groups, Coeliac Society etc. for little financial gain.
Has it been implemented elsewhere?	According to Coeliac UK 40% of ICBs have stopped or restricted prescribing of GF products on prescription. Our neighbouring ICBs Nottinghamshire, Northamptonshire and Derbyshire have all stopped prescribing gluten free product on NHS.
What is the timescale for implementation?	Timescale is dependent on the outcome of the public consultation**.**
Is the proposal a nationally mandated "must-do"?	NHS England guidance on prescribing Gluten-Free foods in primary care states ICBs can restrict further by selecting bread only, mixes only or can choose to end prescribing of all GF foods if they feel this is appropriate for their population, whilst taking account of their legal duties to advance equality and have regard to reducing health inequalities. Although this is not a nationally must-do, more areas across the East Midlands are moving towards or have already removed gluten free food provision from FP10 prescriptions. This area has also be flagged by Region (NHS Midlands and East) as an area where LLR ICB can make prescribing savings. LLR ICB are significantly above the England median across other ICB in cost/1,000 patients for GF prescribing.
Is there evidence to support this proposal, e.g. supported by NICE guidelines? Please specify.	NHS England conducted a consultation and the results were published by the Department of Health & Social Care (DHSC) published in March 2017. Following the consultation, legislation was amended stating all GF food, other than

	bread and mixes, were to be included in Schedule 1 of the "National Health Services (General Medical Services Contracts) (Prescription of Drugs etc.) Regulations 2004. Everything apart from GF bread and mixes is now 'blacklisted' in the England drug tariff and not available for prescribing at NHS expense within England. Under the amended legislation, **ICBs can restrict further by selecting bread only, mixes only or can choose to end prescribing of all GF foods** if they feel this is appropriate for their population, whilst taking account of their legal duties to advance equality and have regard to reducing health inequalities. There are ICBs across England who have opted to review their stance on gluten free products including stopping GF products all together due to the reason stated above.

SECTION 5: STRATEGY

Which of the LLR Quintuple Aims does this proposal meet?		How does it meet this aim?
Enhance experience of care	x□	Patients requesting prescriptions may be disappointed. Not all patient access GF products on prescription and manage a naturally GF diet. The support needed if the decision is to stop prescribing will be based on the outcome of the public consultation
Enhance the Health and wellbeing of the LLR population	X□	Yes - By promoting self-care and a

		naturally gluten free diet
Reduce per Capita cost of Healthcare + Improve Productivity	X□	Yes - Annual savings or pro rata saving from the date the decision is implemented
Address Health + Care Inequalities	X□	To be informed by public consultation process
Increase the Well-being + Engagement of the Workforce	□	N/A

Which of the 10 System Expectations does the proposal meet and how does it meet them?	
Safety First Approach	A safe alternative is available without prescription or from a naturally Gluten free diet
Equitable Care for All	NA
Involve our Patients and Public	Through Public Consultation
Have a Virtual by default Approach	NA
Care in local settings	NA
Provide Excellent Care	NA
Enhanced Care in the Community	NA
Have an Enabling Culture	Encourages self-management and reduced reliance in NHS resources
Drive technology, Innovation and Sustainability	NA
Work as One system with a System Workforce	LLR wide approach to the provision of GF food at NHS expense

Additional Comments

There will need to be a Public Consultation exercise to provide people with an opportunity to be involved and shape proposals for change and improvement and to comment on those proposals before any final decisions are made. This includes those who use services, their carers and advocates; the voluntary, community and social enterprise sector, local government; community leaders and stakeholders, NHS partners and NHS staff.

The final decision influenced by the insights collected through the public consultation will need to be communicated to those patients accessing GF foods on FP10 prescriptions.

If the decision is made to stop gluten free prescribing then the prescribing support tools, the LLR formulary and Policy would be updated to reflect the changes

In addition, work with Dietetic colleagues would be undertaken to update the existing guidance to reflect any change.

LLR FP10 annual prescribing costs for GF products for 22/23 was £259,832

Commissioner / Provider plus Code	Spend	Items	AIV
ELR	££92,904	4,526	£20.53
WL	£103,145	5,196	£19.85
LC	£63,784	3,685	£17.31
LLR	**£259,832**	**13,407**	**£19.38**

If approved the saving will the annual spend or pro rata for the remainder of the year

SECTION 6: WORKFORCE

What is the WTE change that is being proposed? *Provide a breakdown of costings here:*	N/A
What is the rationale/justification for the change? *Provide details of use of staff to deliver the project and why additional staff are required*	N/A
What is the source of the workforce supply? E.g. newly qualified from DMU, international recruitment etc.	N/A

What is your current underlying vacancy position?	N/A
How will the recruitment of additional staff improve the experience of the workforce, in terms of career development pathways, wellbeing at work, reduction in staff absence etc?	N/A
What actions have currently been taken to close the gap?	N/A
How do you plan to promote Equality and Diversity?	N/A
Describe any dependencies, interdependencies or competing demand for staff that you are aware of?	N/A

Note: capture any workforce-related risks in the risks section.

SECTION 7: FINANCES

Key Metrics *(from accompanying excel workbook)*

	Value £000	As a % of existing service cost
Current Cost of Service	NA	100%
Additional Investment (total over 3 Years)	NA	
Savings created (total over 3 Years)	NA	

	Value £000	As a % of existing service cost
Annual Recurrent Investment (Year 3 onwards)	NA	
Annual Recurrent Savings (Year 3 onwards)	NA	
Net Recurrent Savings (Year 3 onwards)	N/A	

Recurrent Savings as a proportion of existing service costs	NA
Recurrent Savings as a proportion of investment made	NA

Payback Period	NA
Year in which net in year savings commence	NA

Will it deliver savings?	Y	If it is not delivering savings, is it cost neutral?	N/A	What is the return on investment?	N/A
Investment	Public consultation cost required. Other investment not required				
Will the project take cost out of the system? If so, give details.	N/A For example, does the project propose to deliver a service in a manner that is at reduced cost? In which organisation will those saving materialise and when.				
Will savings be recurrent or none recurrent?	Non recurrent – Medicine optimisation efficiency only takes into account full 12 month effect. Even though this efficiency will continue it will not be recurrent due to the way the budget is set. Please use table below to show profiling for year 1. (ensure "Summary" Tab and "Summary by Organisation tab within the excel template are complete)				
Please outline any Growth Assumptions	**N/A**				

Month (£'000s)												
	Apr	May	Jun	Jul	Aug	Sept	Oct	Nov	Dec	Jan	Feb	Mar
Gross Savings												
Investment												
Net Savings												

How will savings be delivered?	
Activity reduction	(give details i.e. Activity Currency for instance non-HRG or HRG and POD) N/A
Financial	(give details i.e. budget reduction) Budget Reduction of £259,832 based on 2022-2023 spend on GF products across LLR.

	If approved the saving will be estimated at £21,653 per month saving based on annual spend of 2022/2023 or pro rata for the remainder of the year.

Schedules showing the investment, (pay & non pay) and savings impact, in each of the three system partners is shown in tab "Summary by Organisation" within the accompanying spreadsheet.

SECTION 8: IMPACT ASSESSMENTS

You must complete the impact assessments below and they must be signed off by your Quality Team.

SECTION 8.1: QUALITY IMPACT ASSESSMENTS (QIA) – SEE ATTACHED DOCUMENT

Risks to Patient Safety: Does the scheme minimise harm and risk to patients?	Details (include mitigation)	Consequence	Likelihood	Score
	Is there any impact to vulnerable patients?			
	Will the scheme impact on the safeguarding of Adult or Children?			
	Is patient safety in any way compromised by the scheme?			
	Is there any impact on the processes for preventing Healthcare Associated Infections or other related harm? (e.g. MRSA / CDI, falls etc)			

Risks to Clinical Effectiveness: Is the scheme the application of best	Details (include mitigation)	Consequence	Likelihood	Score
	Under the amended legislation, CCGs can restrict further by selecting bread only, mixes only or can choose to			

knowledge, derived from research?	end prescribing of all GF foods if they feel this is appropriate for their population, whilst taking account of their legal duties to advance equality and have regard to reducing health inequalities.			
	Does the scheme result in shorter lengths of hospital stays?			
	Does the scheme improve the patient's clinical outcome?			
	Does the scheme result in a higher likelihood of recovery?			
	Does the scheme provide better access to wider care pathways?			

Risks to Patient Experience: Will the scheme offer a positive experience of care?	Details (include mitigation)	Consequence	Likelihood	Score
	Does the scheme result in a more positive experience for patients?			
	Does the scheme result in better access to services for patients?			
	Does the scheme require any level of public and/or patient engagement?			
	Does the scheme require patients or their carers to travel further to access services?			
	Will there be any impact on cleanliness and general environmental standards?			

Overall Risk Score (highest from above quality domains)	

Sign Off	Signature	Date
- Chief Nurse and Quality Lead		
Project Lead		

Likelihood	Consequences				
	1 (Insignificant)	2 (Minor)	3 (Moderate)	4 (Major)	5 (Catastrophic)
1 (Rare)	1	2	3	4	5
2 (Unlikely)	2	4	6	8	10
3 (Possible)	3	6	9	12	15
4 (Likely)	4	8	12	16	20
5 (Almost certain)	5	10	15	20	25

Consequence scores: 1 Insignificant, 2 Minor, 3 Moderate, 4 Major, 5 Severe

Likelihood scores: 1 Rare, 2 Unlikely, 3 Possible, 4 Likely, 5 Almost Certain

Assurance Checklist	Comment
What impact does the scheme have on workforce capacity?	Does not have impact on workforce
How value maximised and waste is minimised?	Provision on prescription will stop
How can the improvements be shared between primary and secondary care?	N/A
If appropriate, have discussions been held regarding the impact on stakeholder relationships? (which committee, providers etc)	Previous discussion has taken place when last consultation had taken place. Meetings have been held with Coeliac UK, who have influenced the public consultation approach. Also Healthwatch organisations. Further work is required with Joint Health Overview and Scrutiny Committee to get their views of the proposal.
Has the named Clinical Lead, with responsibility for safety and quality input to the service specification / project design?	N/A
Are the plans underpinned by National evidence based guidance such as NICE or supported with a JSNA?	Yes – National consultation 2017- included guidance from NHSE with the option to further restrict prescribing of GF products on prescription
How will the delivery of quality within the scheme be measured? (Quality Schedule, KPI's)	GF products will no longer be provided in FP10 prescriptions therefore savings will be estimated based on previous year's annual spend on GF items on prescription. Please note this is not a quality improvement scheme.
How does the scheme support continuous quality improvement and enable sustainability?	Saving from this scheme could be used to enable delivery of system priorities and the health prevention program.
How is clinical engagement enhanced through adoption of the scheme?	Through Public Consultation
Has the clinical lead reviewed the potential impact of prescribing and medicines optimisation?	The business case proposal comes from the Integrated Medicines Optimisation Design Group and is reviewed by members including GP prescribing leads, pharmacists and technicians.
Have any unintended consequences been identified? What contingencies are in place to mitigate these?	Opposition has come from Coeliac UK, patients groups and some clinical staff. We have moved from an engagement approach

	to public consultation to better understand the impact of the proposed change. Further insights may come through public consultation which would influence the final decisions made and further mitigations would be introduced.

Sign Off	Signature	Date
Chief Nurse and Quality Lead		
Project Lead		

SECTION 8.2: EQUALITY IMPACT ASSESSMENT (EIA):

EQUALITY, HEALTH INEQUALITY IMPACT AND RISK ASSESSMENT

Please complete all sections

Guidance documents available

Start date: 14/03/24	Completed data: 14/03/2024		
Who is impacted by the service / project / change?	**Yes**	**No**	**Indirectly / Possibly**
Patients, Service Users	**x**		
Carers or Family	**x**		
General Public		No	
Staff	**x**		
Partner Organisations		No	

Summary information of the service / policy / function being assessed:

Stop the provision of Gluten Free (GF) bread and mixes on prescription and promote self-care and naturally available gluten-free diet.

Aims and objectives of service / policy / function:

In 2016-2017 a review of Gluten free prescribing policy was consulted on with two options. Option 1 stop all GF prescribing or option 2 allow up to 8 units each month of Bread or flour mix only.

Option 2 was agreed as the outcome.

More areas across the East Midlands are moving towards or have already removed gluten free food provision from FP10 prescriptions. According to Coeliac UK “Around 60% of all policy areas in England offer gluten free prescribing [18] in line with the DHSC decision to retain bread and flour mix in 2017. Wales, Scotland and Northern Ireland prescribe gluten free staples in line with national prescribing guidelines.”

Historically, availability of gluten free foods was limited, therefore obtaining these products from community pharmacies via prescriptions improved access to them. With the increased awareness of coeliac disease and gluten sensitivity as well as a general trend towards eating less gluten, these products are now much more widely available than before.

All major supermarkets and many other retailers now commonly stock gluten free foods as well as other special diet alternatives both online and in-store. Furthermore, improved food labelling now means people are able to see whether ordinary food products are free from gluten and can be safely eaten.

The price paid by the NHS for gluten free foods on prescription is much higher than the supermarket prices available to the public.

We acknowledge that gluten free food products are often more expensive than their gluten containing equivalents. However, It is possible to eat a gluten free diet that follows the Eatwell Guide model for balanced eating without the need for any specialist dietary foods, simply by choosing naturally gluten free carbohydrate containing foods (e.g. rice and potatoes) as part of a healthy balanced diet.

The main aim and objective is to go through a public consultation process to inform a decision on whether to stop GF prescribing on NHS.

If this assessment relates to a review / current service or policy, what are the main changes proposed and reason why: Review of policy – current policy allows GF bread and mixes on prescription. The main change proposed is to stop all GF products on prescription.

What engagement work is planned / or carried out and how will you involve people from equality groups to ensure that their views inform decision making: The proposal will go through public consultation process (this will be led by the communication and engagement team) Comms will reach out to all communities including those with protected characteristics and the vulnerable.
Does the proposal or change help to reduce health inequalities? No, while the aim of the proposal is not to reduce health inequalities, the public consultation process and impact assessment will ensure due regard is taken.
Does the proposal relate to impacts due to COVID-19? NO **If yes, please summarise these:**
Evidence section
What evidence have you considered within this assessment? (this can include NICE / research / engagement work / demographics) – In 2016-2017 a local review of Gluten free prescribing policy was consulted on with two options. Option 1 stop all GF prescribing or option 2 allow up to 8 units each month of Bread or flour mix only. Option 2 was opted from that consultation. Further on NHS England conducted a consultation In March 2017, the Department of Health & Social Care (DHSC) published the consultation with the option chosen was to restricts GF prescriptions to certain bread and mixes. Therefore, under current legislation all GF food, other than bread and mixes, will be included in Schedule 1 of the "National Health Services (General Medical Services Contracts) (Prescription of Drugs etc.) Regulations 2004. This means that everything apart from GF bread and mixes is 'blacklisted' in the England drug tariff and not available for prescribing at NHS expense. Under the amended legislation, ICBs can restrict further by selecting bread only, mixes only or can choose to end prescribing of all GF foods if they feel this is appropriate for their population, whilst taking account of their legal duties to advance equality and have regard to reducing health inequalities. Evidence from Coeliac UK on the significance of gluten free diet: Coeliac disease is an autoimmune disease caused by a reaction to gluten, found in wheat, barley and rye. Adherence to the gluten free diet remains the complete medical treatment and having coeliac disease therefore requires significant dietary modification. Rates for

adherence to the gluten free diet can vary between 42-91% and access to gluten free staples on prescription can be related to adherence.

Following a strict gluten free diet allows the gut to heal and reduces the risk of long-term complications. Non adherence to the gluten free diet is associated with an increased risk of long term complications, including osteoporosis, ulcerative jejunitis, intestinal malignancy, functional hyposplenism, vitamin D deficiency and iron deficiency. For children, non-adherence to the diet can have additional consequences including faltering growth and delayed puberty. These long-term complications will impact upon quality of life for the patient and treating these complications will have financial implications for the NHS.

If this assessment relates to a policy / strategy, has an equality statement been added or planned to be added? **If no, please state why not:**	Part of consultation process.

IMPACT ASSESSMENT:

This section should record any known or potential impacts on equality groups and other groups at risk of poorer health outcomes. Impacts may be both negative and positive. Think about barriers to access and how different groups may be disproportionately impacted. You can copy and paste this tick: ✓

Age	**Positive effect**	**Negative effect**	**Neutral**
		✓	

Explanation: This equality group could be impacted as prescription charge exemptions are age-related. This would include prescriptions for GF food. Those aged under 16 years of age, those aged 16, 17 and 18 in full time education, and those aged 60 or over are eligible for prescription exemptions. The age-related exemptions are for all prescription items and are not unique to GF prescribing.

There is also potential long-term impact of non-adherence to gluten free diet Coeliac UK suggest that osteopenia or osteoporosis are found in 40% of adult patients at diagnosis of coeliac disease.

Stopping GF products will have impact on all age groups and will apply to all protected groups. Since the national publication there has been a national drive for self-care and patients are now advised to buy more items over the counter.

Disability	**Positive effect**	**Negative effect**	**Neutral**
		✓	
Explanation: There is no routinely collected data on prescribing and disability so we cannot definitively assess fully. Some patients with an existing medical condition are exempt from prescription charges and hold a medical exemption certificate. GF is more widely available than before, and patients could obtain GF food when travelling to the supermarket or having their regular shopping delivered. Coeliac UK evidence suggests that there is a sparsity in rural and deprived areas and having to visit more supermarkets to obtain GF products and budget supermarkets have less choice. Also, transport may be an issue for those who have a disability and accessing GF products. **People with certain conditions, including type 1 diabetes, autoimmune thyroid disease, Down's syndrome and Turner syndrome, have an increased risk of getting coeliac disease.**			
Sexual Orientation	**Positive effect**	**Negative effect**	**Neutral**
			✓
Explanation: This equality group will not face discrimination in this area of work as the prescribing changes will impact on all coeliac patients.			
Gender Reassignment	**Positive effect**	**Negative effect**	**Neutral**
			✓
Explanation: It is unlikely that this equality group will face discrimination in this area of work as the changes to GF prescribing will impact on all coeliac patients.			

Sex	**Positive effect**	**Negative effect**	**Neutral**
		✓	
Explanation: Unsure as we cannot accurately assess the impact at a local level. Coeliac disease can affect both men and women, NHS Choices states that reported cases of coeliac disease are two to three times higher in women than men. This would mean that women could potentially be more impacted than men. However, any changes will apply to all patients regardless of their sex and the changes to stop prescribing of GF foods will apply to all protected groups.			
Race	**Positive effect**	**Negative effect**	**Neutral**
		✓	
Explanation: Patients from all racial groups can be affected by coeliac disease. Estimates of patients reflecting the general population of England indicate that 87% are of "white ethnic origin". No evidence has been found that patients from specific racial groups have higher rates of diagnosis of coeliac disease, meaning that the policy of stopping prescribing of GF foods will not discriminate against people from different racial backgrounds. Any changes will apply to all patients regardless of their race.			
Religion and Belief	**Positive effect**	**Negative effect**	**Neutral**
			✓
Explanation: This equality group will not face discrimination in this area of work as the prescribing changes will impact on all coeliac patients.			
Pregnancy and Maternity	**Positive effect**	**Negative effect**	**Neutral**
		✓ (short-term)	

Explanation: 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. However, the prescribing changes will impact on all coeliac patients.

Marriage and Civil Partnership	**Positive effect**	**Negative effect**	**Neutral**
			✓

Explanation:

This equality group will not face discrimination in this area of work as the changes to GF prescribing will impact on all coeliac patients regardless of marriage and civil status.

Other groups at risk of poorer health outcomes:

Carers	**Positive effect**	**Negative effect**	**Neutral**
		✓	

Explanation: There is no data available on the number of carers (of adults or children) who are currently prescribed GF food. 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. Carers will be able to access GF food in supermarkets or other outlets alongside their usual shopping.

Socio-economic deprivation	**Positive effect**	**Negative effect**	**Neutral**
		✓	

Explanation:

Difficult to assess a link between patients who receive prescription and whether they live in a deprived area. Further work may need to be to be completed to assess the full impact.

Historically, availability of gluten free foods was limited, therefore obtaining these products from community pharmacies via prescriptions improved access to them. With the increased

awareness of coeliac disease and gluten sensitivity as well as a general trend towards eating less gluten, these products are now much more widely available than before.

All major supermarkets and many other retailers now commonly stock gluten free foods as well as other special diet alternatives both online and in-store. Furthermore, improved food labelling now means people are able to see whether ordinary food products are free from gluten and can be safely eaten.

Families on Low Income - Families who are on low incomes are likely to feel a greater impact from any changes to the current system for the prescribing of GF foods as they may currently be eligible for exemptions from prescription charges. Some families may have multiple coeliac disease patients making an increased cost to their weekly food shopping bill likely, if GF prescribing was ended and they had to purchase GF foods.

According to Coeliac UK the cost especially for GF bread is still comparably higher than non GF alternative (please see below).Natural GF foods are usually bought within the grocery shopping such as rice and potatoes. Mitigation is to support with health messages around alternative foods

- A gluten free loaf of bread is on average 4.3 times more expensive than a standard gluten containing loaf
- The cheapest gluten free loaf of bread is 7.2 times more expensive than the cheapest gluten containing loaf
- A weekly gluten free food shop can be as much as 20% more expensive than a standard weekly food shop

Campaign to make gluten free food more affordable and more accessible - Coeliac UK's campaign for more affordable and more accessible gluten free food - Coeliac UK

Other groups e.g. Asylum Seekers, Homeless, Sex Workers, Military Veterans, Rural communities – please state	**Positive effect**	**Negative effect**	**Neutral**
		✓ (Can be linked to socio-economic groups, see above)	

Explanation:

See above.

Equality Legal Duties – compliance

Has the ICB given due regard and given consideration for the following:

Eliminating unlawful discrimination, harassment, and victimisation Unlawful discrimination takes place when people are treated 'less favourably' as a result of having a protected characteristic	Yes
Advancing equality of opportunity between people who share a protected characteristic and those who do not Making sure that people are treated fairly and given equal access to opportunities and resources	Yes
Fostering good relations between people who share a protected characteristic and those who do not Creating a cohesive and inclusive environment for all by tackling prejudice and promoting understanding of difference	Yes
Are there any potential Human Rights concerns If yes – please seek advice from the E&I team to discuss carrying out specific human rights assessment	No
Compliance to the NHS Contract In relation to Service Conditions (SC13) which includes Accessible Information Standard	Yes

Supporting narrative to support the above responses: This section must be completed – This decision relates to everyone meeting the requirements for provision of GF bread and mixes on FP10 prescription regardless of any protected characteristics or any of the concerns above.

Equality Related Risk Assessment Section

If you have identified an equality risk, please use the table below to work out the risk score. If you have a score of 9 and above you should escalate to risk management procedures.

	Level of risk				
Level of consequence	RARE: 1	UNLIKELY: 2	POSSIBLE: 3	LIKELY: 4	VERY LIKELY:5
1. Negligible	1	2	3	4	5
2.Minor	2	4	6	8	10
3.Moderate	3	6	9	12	15
4.Major	4	8	12	16	20
4.Catastrophic	5	10	15	20	25

If you have identified an equality risk: What is the consequence? What is the likelihood? Risk score = consequence x likelihood	Risk Score = Will re-visit after consultation process
Any narrative relating to risk score: Equitable decision across patient group regardless of protected characteristics.	

Equality Action Plan with target dates

Please include any related recommendations arising from this assessment. A target date is required for all actions

Action required	Lead person	Target date	Further comments
Complete Consultation process exercise before progressing	Engagement Team	TBA	

Date for this assessment to be shared with governance processes: **DD/MM/YYYY**

(All assessments should have governance oversight)

Final Section: Approval from Equality and Inclusion Team

Date received by E&I Team for assurance check: 14/03/24

Person completing the assessment template: Hamza Ismail and Anne-Marie Harrison

Date and E&I Team member completing assurance check: Shaun Cropper 02/09/21 & 10/06/23& 14/03/24, 16/05/24

What next?

1. Regularly review the action plan and update EHIIRA accordingly
2. Save a finalised copy for your records and share with your governance processes and the E&I Team / E&I Business Partner
3. Follow any internal advice from the E&I Team – if provided

SECTION 9: SCOPE AND PLANNING ASSUMPTIONS

Scope and Exclusions	**Scope: do we continue GF prescribing or stop GF prescribing on FP10**
Planning Assumptions	Based on decision after the consultation

SECTION 10: INFORMATION TECHNOLOGY & GOVERNANCE

Please state for each relevant sections how the IT interdependencies has been assessed

Intra-operability with existing systems	***N/A***
Data Management & Reporting arrangements	*N/A*
Data Security & Data Sharing Arrangements	*N/A*
Digital Technology Interface Requirements	*N/A*

SECTION 11: PROJECT PLANNING

SECTION 11.1: DELIVERY PLAN

Please outline the key delivery milestones from your delivery plan required to deliver the project. Please assign expected start and end dates.

Key Project Milestones				
No	Milestone	Owner	Start Date	End Date
1.	Public Consultation	Sue Venables	3rd June	14 July
2.	Depending on the result if the preferred option then giving an advance notice of stopping GF products and sharing the communication with patients and stakeholders	TBC	TBC	TBC
3.				
4.				

5.				
6.				
7.				
8.				
9.				
10.				

SECTION 11.2: RISKS TO DELIVERY

Capture all risks here that score 12 or above, using the matrix below.

Risk	Description	Owner	Consequence	Likelihood	Risk Score (Consequence x Likelihood)	Mitigation of risk
Identify risks from impact assessments and any risks that fall outside of the impact assessment process and log them below. Please refer to the example below for the risk description wording and also refer to the risk matrix to assist with risk scoring.						
0	There is a risk that: CAUSE If this occurs this may result in: EFFECT	A.N Other	**Impact** 1=Negligible, 2=Minor, 3=Moderate, 4=Major, 5=Catastrophic **Likelihood** 1=Rare, 2=Unlikely, 3=Possible, 4=Likely, 5=Almost Certain			
1	There is a risk that opposition from patients and charities such as Coeliac UK on the preferred option will be raised and may result in complaints		2	3	6	Work with Coeliac UK, Healthwatch organisations, patient groups, VCSE and staff to implement the public consultation.
2	There is a risk that some patients may not follow a GF diet and who may develop complications of the condition from non-adherence to a GF diet		3	2	6	This is likely to be the case already as only bread and flour mix are provided.
3	There is a risk that this policy could impact on lower income families maintaining a GF diet		3	2	6	Only bread and flour mix on prescription. Impact may be seen due to the current cost of living and inflation

4.	Risk that Joint Health Overview and Scrutiny Committee doesn't support intention to consult		3	3	9	Work with the Local Authorities to gain their support of approach
5.	Proposals impacted by new guidance on transformation programmes introduced by Secretary of State.		3	3	9	Work with Department of Health and NHS England to assess implications. If it comes under new guidance, forms and evidence will be required and sent to Secretary of State

Likelihood	Consequences				
	1 (Insignificant)	2 (Minor)	3 (Moderate)	4 (Major)	5 (Catastrophic)
1 (Rare)	1	2	3	4	5
2 (Unlikely)	2	4	6	8	10
3 (Possible)	3	6	9	12	15
4 (Likely)	4	8	12	16	20
5 (Almost certain)	5	10	15	20	25

SECTION 11.3: KEY PERFORMANCE INDICATORS

No	Key Performance Indicator	Outcome	Baseline	Target	Reporting Frequency
1.	Public Consultation	System decision	N/A	N/A	Once
2.	Stop GF prescribing	Depending on Consultation and/or Engagement. If the preferred option is chosen then there is no FP10 prescribing on any GF products	Current spend	0 prescription	Once a month for three months post change
3.					
4.					

5.					
6.					
7.					

SECTION 11.4: SYSTEM-ALIGNED OUTCOME MEASURES

No	Outcome Measure	Baseline	Target	Reporting Frequency
1.	Efficiencies delivered	£259k per annum	0 spend	
2.				
3.				
4.				
5.				
6.				
7.				

SECTION 11.5: SAFEGUARDING

Please complete, as relevant.

How will the service demonstrate its responsibilities regarding:

- safeguarding children, young people and adults at risk
- the Mental capacity act
- looked-after children?

This is not a service. It is a formulary decision therefore this will not be applicable

How will the service demonstrate joint working between agencies and professionals to promote effective safeguarding practice?

This is not a service. It is a formulary decision therefore this will not be applicable

SECTION 12: ORGANISATIONAL CONTACTS

Who have you worked alongside to draft this Business Case? Place a tick against each of the function areas below and state the contact name who can support the information included within this business case		
	Name	Organisation
☐ Clinical	LPT dietician, Coeliac UK, IMODG	ICB/UHL/LPT
☐ Finance	Andrew Roberts	ICB
☐ Performance		
☐ Business Intelligence		
☐ Procurement		
☐ Contracts		
☐ Strategy & planning	Nigel Brady /Amit Sami	ICB
☐ Integration & Transformation		
☐ Communications	NA	
☐ Engagement and Patient Experience	Jo Ryder/Susan Venables	ICB
☐ Safeguarding		
☐ Provider	Dietetics/ Gastroenterology	LPT/ UHL
☐ Equality and Diversity	Shaun Cropper	
☐ Quality	Chris West	
☐ Estates and Facilities	NA	
☐ Voluntary Sector	NA	
☐ IM&T	NA	

SECTION 13: FINAL REVIEW & RECOMMENDATION

Only to be completed by the System Planning Operational Group (SPOG).

Considerations	Yes/No
Does it align to the Quintuple Model and the Ten System Expectations?	
Does the project require investment? If yes; Does it deliver financial savings at least equal to the investment?	

Is it robust, risk assessed and achievable?	
Have all impact assessments been completed?	

Recommendation	
Comments from the System Transformation Steering Group	
Recommended next steps	
Date	