Commissioning Policy

NHS Redditch and Bromsgrove Clinical Commissioning Group

NHS South Worcestershire Clinical Commissioning Group

NHS Wyre Forest Clinical Commissioning Group

Faecal Calprotectin Testing

for Suspected Irritable Bowel Syndrome (IBS) or Inflammatory Bowel Disease (IBD)

October 2019

This policy applies to patients for whom the following Clinical Commissioning Groups are responsible:

- NHS South Worcestershire Clinical Commissioning Group (CCG)
- NHS Redditch & Bromsgrove Clinical Commissioning Group (CCG)
- NHS Wyre Forest Clinical Commissioning Group (CCG)

Collectively referred to as the Worcestershire CCGs

COMMISSIONING SUMMARY

Faecal calprotectin testing for suspected IBS/IBD is commissioned when:

a. Patient is aged 16 to 50 years AND
b. Patient has on-going or recurrent symptoms (abdominal pain, bloating, change in bowel habit, diarrhoea/loose stool) over at least 6 weeks AND
c. 2WW symptoms have been excluded AND
d. Initial investigations (FBC, ESR, CRP, LFT, TSH, U&Es, TTG) have been undertaken AND
e. Stool microscopy and culture (if diarrhoea) has excluded an infectious cause

Where all initial investigations are normal, a patient should be treated as IBS over a period of at least 4 weeks.

A faecal calprotectin test is indicated when:

a. Isolated raised CRP/ESR following initial investigations OR
b. Normal investigations and unsuccessful treatment for IBS over at least 4 weeks (including diet and lifestyle advice and pharmacological treatment) OR
c. Initial faecal calprotectin test result between 100 and 500 mcg/g (test should be repeated at 4-6 weeks following the first test)

Further detail including requirements prior to testing, necessity for a repeat test and actions arising from faecal calprotectin test results is outlined in section 5 of this document.

Referral to gastroenterology is recommended when:

a. Index faecal calprotectin > 500mcg/g
b. Repeat faecal calprotectin > 100mcg/g
c. Index and/or repeat faecal calprotectin < 100mcg/g but patient remains symptomatic despite management in accordance with IBS

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Document Details:

Version:	1.0
Ratified by (name and date of Committee):	Clinical Executive Joint Committee – 30/10/19
Date issued:	28/11/19
Internal Review Date:	Documents will be reviewed as a minimum every 3 years. However, earlier revisions to the policy may be made in light of published updates to local and national evidence of effectiveness and cost effectiveness and/or recommendations and guidelines from local, national and international clinical professional bodies. Date to Initiate Review: 30/10/2022
Lead Executive/Director:	Simon Gartland
Name of originator/author:	Fiona Bates
Target audience:	Patients, GPs, Optometrists, Secondary Care and Primary Care (Community) Providers, Independent Sector Providers
Distribution:	GPs, Secondary Care Providers
Equality & Diversity Impact Assessment	02/10/19

Key individuals involved in developing the document:

Name	Designation	Version Reviewed
Fiona Bates	Specialist Medicines and Clinical Policy Adviser, Worcestershire CCGs	1.0
Helen Bryant	Senior Contracts Manager, Worcestershire CCGs	1.0
Danny Cheung	Consultant Gastroenterologist, Worcestershire Acute Hospital Trust	1.0
Kirsty Hinton	Programme Delivery Manager, Worcestershire CCGs	1.0
Andrew Milestone	Consultant Gastroenterologist, Wye Valley Trust	1.0

Circulated to the following individuals/groups for comments:

Name	Date	Version Reviewed
Clinical Commissioning Policy Collaborative, which includes: GPs, Commissioners, Medicines Commissioning, Public Health, Patient and Public Representatives	October 2019	1.0
Clinical Innovation Group	October 2019	1.0

Version Control:

Version No	Type of Change	Date	Description of change

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1. Definitions

1.1 **Faecal Calprotectin** - a protein that is released extracellularly at sites of inflammation. It is only found in plasma and faeces therefore it is more specific than other markers of inflammation currently available

1.2 **Inflammatory Bowel Disease** (IBD) – is a term mainly used to describe two conditions: ulcerative colitis and Crohn's disease. Ulcerative colitis and Crohn's disease are long-term conditions that involve inflammation of the gut.

- Ulcerative colitis only affects the colon (large intestine).
- Crohn's disease can affect any part of the digestive system, from the mouth to the anus.

1.3 **Irritable Bowel syndrome** (IBS) – a common condition that affects the digestive system. It causes symptoms like stomach cramps, bloating, diarrhoea and constipation.

1.4 **Exceptional clinical circumstances** are clinical circumstances pertaining to a particular patient, which can properly be described as exceptional, when compared to the clinical circumstances of other patients with the same clinical condition and at the same stage of development of that condition (i.e. similar patients). A patient with **exceptional clinical circumstances** will have clinical features or characteristics which differentiate that patient from other patients in that cohort and result in that patient being likely to obtain significantly greater clinical benefit (than those other patients) from the intervention for which funding is sought.

1.5 A **Similar Patient** is a patient who is likely to be in the same or similar clinical circumstances as the requesting patient and who could reasonably be expected to benefit from the requested treatment to the same or a similar degree. The existence of more than one similar patient indicates that a decision regarding the commissioning of a **service development** or commissioning policy is required of the Commissioner.

1.6 An **individual funding request (IFR)** is a request received from a provider or a patient with explicit support from a clinician, which seeks exceptional funding for a single identified patient for a specific treatment.

1.7 An **in-year service development** is any aspect of healthcare, other than one which is the subject of a successful individual funding request, which the Commissioner agrees to fund outside of the annual commissioning round. Such unplanned investment decisions should only be made in exceptional circumstances because, unless they can be funded through disinvestment, they will have to be funded as a result of either delaying or aborting other planned developments.

2. Scope of policy

2.1 This policy is part of a suite of locally endorsed Commissioning Policies. Copies of these Commissioning Policies are available on the following website address: http://www.redditchandbromsgroveccg.nhs.uk/about-us/strategies-policies-and-procedures/commissioning-ifr/

2.2 This policy applies to all patients for whom the Worcestershire CCGs have responsibility including:

- People provided with primary medical services by GP practices which are members of any one of the CCGs and
- People usually resident in any of the areas covered by the CCG's and not provided with primary medical services by any CCG.

2.3 Where a patient's clinical presentation does not clearly meet the requirements for secondary care referral within the context of this policy, and where a GP is uncertain or concerned about the appropriate treatment/management pathway, referral for Advice & Guidance should be considered as an alternative to a referral for clinical assessment.

2.4 There may be occasions when a GP referral is made for specialist assessment which appears to meet the policy requirements, but which on specialist clinical examination either does not meet the clinical criteria for surgery or is not considered clinically suitable for surgery. Such patients should be discharged without surgery.

2.5 For patients who do not fall within the eligibility criteria set out in the policy but where there is demonstrable evidence that the patient has exceptional clinical circumstances, an Individual Funding Request may be submitted for consideration. The referring clinician should consult the Commissioner's "Operational Policy for Individual Funding Requests" document for further guidance on this process.

For a definition of the term "exceptional clinical circumstances", please refer to the Definitions section of this document.

2.6 This policy applies to patients aged 16 to 50 years with gastric symptoms suggestive of either irritable bowel syndrome or inflammatory bowel disease. It does not apply to people with an established diagnosis of inflammatory bowel disease (IBD) or those aged under 16 years or over 50 years. These patients will be managed either by specialist consultants within secondary care directly (established IBD and age < 16 years) or via alternative pathways ie. faecal immunochemical test (FIT)/2WW/gastroenterology referral.

3. Background

3.1. The NHS Constitution, which details the principles and values that guide the NHS, has been applied in the agreement of this policy.

3.2. NHS Redditch & Bromsgrove Clinical Commissioning Group, NHS South Worcestershire Clinical Commissioning Group and NHS Wyre Forest Clinical Commissioning Group consider all lives of all patients whom they serve to be of equal value and, in making decisions about funding treatment for patients, will seek not to discriminate on the grounds of sex, age, sexual orientation, ethnicity, educational level, employment, marital status, religion or disability except where a difference in the treatment options made available to patients is directly related a particular patient's clinical condition or is related to the anticipated benefits to be derived from a proposed form of treatment.

3.3. The Worcestershire gastroenterology QIPP programme for 2019/2020 prioritised the development of a Lower Gastrointestinal (GI) Common Gastroenterology Conditions Leading to Referral Document. The aim of the document is to act as a support tool for primary care, providing recommended pathways for investigations, management and treatment, in addition to links to patient information, referral templates, local and national guidance.

3.4. In writing the lower GI common conditions document, faecal calprotectin testing in primary care was raised as a key investigation required to support the diagnosis of Inflammatory Bowel Disease (IBD) and Irritable Bowel Syndrome (IBS), which is not currently available in Worcestershire.

3.5. Prior local work, undertaken by Clinical Commissioning Policy Collaborative (CCPC) in 2017, had not supported use of faecal calprotectin due to concerns in the rates of false positives; in 2019 an updated evidence review was completed and determined that this can be avoided through defined use of repeat testing.

3.6. Faecal calprotectin testing changes the way in which patients are managed, avoiding the need for referral and subsequent invasive colonoscopy in many patients. An approved faecal calprotectin pathway has been incorporated into the common conditions document to streamline patient management, detailing required initial investigations and treatment prior to test request.

3.7. Wye Valley Trust were an early adopter of faecal calprotectin testing with availability across Herefordshire for many years. In implementing new commissioning arrangements across Worcestershire, the pathways have been aligned across the two counties.

4. Relevant National Guidance and Facts

4.1 Ulcerative colitis and Crohn's disease are the two most common forms of IBD. The incidence of ulcerative colitis is approximately 10–20 per 100,000 per year, with a reported prevalence of 100–200 per 100,000 people. The incidence of Crohn's disease is around 5–10 per 100,000 per year (and thought to be increasing), with a prevalence of 50–100 per 100,000 people.

4.2 The prevalence of IBS in adults is reported as 10%-20% in the general population. The true prevalence may be higher because many people with IBS symptoms do not seek medical advice. In terms of non-IBD conditions, the percentage of people with IBS is greater in adults than children.

4.3 IBD and IBS are two conditions that present with similar symptoms, making it difficult to differentiate them from each other. Due to the potential serious complications of IBD (and other organic bowel disease), it is important for clinicians to rule it out before being confident a patient is suffering from IBS. There is no definitive test for IBS and it is often referred to as a 'diagnosis of exclusion'. This results in many patients being referred to secondary care for further investigations with negative results (over 60% of colonoscopies are normal in younger patients).

4.4 Faecal Calprotectin (FC) is a simple, diagnostic test that can be used in either primary or secondary care, to help differentiate between inflammatory bowel disease (IBD) and irritable bowel syndrome (IBS).

4.5 Faecal calprotectin is a protein that is released extracellularly at sites of inflammation. It is only found in plasma and faeces therefore it is more specific than other markers of inflammation currently available, mainly C-reactive protein (CRP) and erythrocyte sedimentation rate (ESR). Patients with IBS do not have raised FC levels whereas patients with active IBD do. High levels of FC are shown to correlate well with both endoscopic and histological assessment of disease activity.

4.6 Some factors may elevate FC levels; the most significant of these are infection and Non-Steroidal-Anti-Inflammatory Drugs (NSAIDs).

4.7 The test may also be used to assess a patient's response to treatment and to predict the risk of flare ups of IBD, but this is outside the scope of the policy and agreed pathway.

4.8 NICE published diagnostic guidance for use of faecal calprotectin testing in 2013 but much more literature has emerged since this time and management pathways refined to improve the sensitivity and specificity of the test.

4.9 Since publication of NICE diagnostic guidance, the evidence to support use of faecal calprotectin testing has been reviewed and summarised in a series of papers considered by the Worcestershire Clinical Commissioning Policy Collaborative.

5. Patient Eligibility

5.1 Local pathways for management of patients with suspected IBS/IBD are available via websites or Clarity TeamNet. The following describes the commissioned testing arrangements:

5.2 Faecal calprotectin testing for suspected IBS/IBD is commissioned when:

a. Patient is aged 16 to 50 years AND
b. Patient has on-going or recurrent symptoms (abdominal pain, bloating, change in bowel habit, diarrhoea/loose stool) over at least 6 weeks AND
c. 2WW symptoms have been excluded AND
d. Initial investigations (FBC, ESR, CRP, LFT, TSH, U&Es, TTG) have been undertaken AND
e. Stool microscopy and culture (if diarrhoea) has excluded an infectious cause

5.3 Where all initial investigations are normal, a patient should be treated as IBS over a period of at least 4 weeks.

5.4 A faecal calprotectin test is indicated when:

a. Isolated raised CRP/ESR following initial investigations OR
b. Normal investigations and unsuccessful treatment for IBS over at least 4 weeks (including diet and lifestyle advice and pharmacological treatment) OR
c. Initial faecal calprotectin test result between 100 and 500 mcg/g (test should be repeated at 4-6 weeks following the first test)

5.5 Prior to faecal calprotectin testing:

a. An infectious cause must be excluded AND
b. NSAIDs should be stopped 2 weeks prior to testing, where possible (this is particularly important where a repeat test is being undertaken)

5.6 Faecal calprotectin test results:

< 100mcg/g - indicates normal result; manage as IBS
100-500mcg/g - uncertain result; repeat faecal calprotectin test at 4-6 weeks
> 500mcg/g - abnormal result; refer to gastroenterology

5.7 Referral to gastroenterology is recommended when:

a. Index faecal calprotectin > 500mcg/g
b. Repeat faecal calprotectin > 100mcg/g
c. Index and/or repeat faecal calprotectin < 100mcg/g but patient remains symptomatic despite management in accordance with IBS

5.8 Referrals to gastroenterology will be triaged according to clinical history and faecal calprotectin results. Where a referral is received without a faecal calprotectin test result (as above) a GP may be asked to organise a test prior to acceptance of the referral; this will be guided by the clinical circumstances.

5.9 Local pathways are available separately to support management of patients in accordance with the above arrangements.

5.10 These arrangements do not override overall clinical responsibility of the referring clinician who may determine that alternative management is more appropriate.

5.11 Providers who undertake faecal calprotectin testing are required to meet the appropriate service delivery requirements for faecal samples, testing and reporting.

6. Supporting Documents

- Worcestershire CCGs: Operational Policy for Individual Funding Requests
- Worcestershire CCGs: Prioritisation Framework for the Commissioning of Healthcare Services
- NHS England: Ethical Framework for Priority Setting Resource Allocation
- NHS England: Individual Funding Requests
- NHS Constitution, updated 27th July 2015
- Worcestershire Clinical Commissioning Policy Collaborative Evidence Reviews:
  - Faecal calprotectin: Assessment of Implications arising from NICE Diagnostic Guidance - January 2014
  - Evaluation of Faecal Calprotectin Testing in Worcestershire – June 2017
  - Faecal Calprotectin in Primary Care – August 2019

7. Equality Impact Assessment

Organisation	Worcestershire CCGs		
Department	Contracting & Transformation Teams	Name of lead person	Fiona Bates
Piece of work being assessed	Faecal Calprotectin Testing for Suspected Irritable Bowel Syndrome (IBS) or Inflammatory Bowel Disease (IBD)		
Aims of this piece of work	To provide guidance to patients and clinicians on the use of Faecal Calprotectin Testing in primary care to assist in the diagnosis of Inflammatory Bowel Disease (IBD)		
Date of EIA	02/10/2019	Other partners/stakeholders involved	Helen Bryant
Who will be affected by this piece of work?	Patients with suspected IBD or IBS, GPs considering referral into secondary care to determine a diagnosis and treatment plan, Secondary Care clinicians who review, advise and treat patients with suspected or diagnosed IBD/IBS.		

Single Equality Scheme Strand	**Baseline data and research on the population that this piece of work will affect.** What is available? E.g. population data, service user data. What does it show? Are there any gaps? Use both quantitative data and qualitative data where possible. **Include consultation with service users wherever possible**	**Is there likely to be a differential impact?** Yes, no, unknown
Gender	There is little gender difference in the prevalence of IBD. IBS is twice as common in women as in men. The policy and pathway do not differentiate between the genders of patients but provides guidance on the options available to them based on their clinical presentation.	No
Race	IBD is more common in white people than in African-Caribbean people or those of Asian origin. The condition is most prevalent in Jewish people of European origin. The policy and pathway do not differentiate between the races of patients but provides guidance on the options available to them based on their clinical presentation.	No
Disability	There does not appear to be any correlation between a patient having a disability and IBD or	No

	IBS, however, it is recognised that the diseases can be debilitative in nature. The policy and pathway do not differentiate between the various disabilities that patients may have but provides guidance on the options available to them based on their clinical presentation.	
Religion/ belief	There does not appear to be any correlation between a patient's belief system or faith and the incidence of IBD or IBS. The policy and pathway do not differentiate between the various belief system or faith that patients may have but provides guidance on the options available to them based on their clinical presentation.	No
Sexual orientation	There does not appear to be any correlation between a patient's sexual orientation and the incidence of IBD or IBS. However, it is acknowledged that the impact of these conditions differ across patient groups. The policy and pathway do not differentiate between patient's sexual orientation but provides guidance on the options available to them based on their clinical presentation.	No
Age	The ratio of Crohn's disease to ulcerative colitis varies between adults and children. In adults, the ratio of Crohn's disease to ulcerative colitis is 2:3, while the ratio in children is much higher (2.3:1). IBS most commonly affects people between the ages of 20 and 30 years; recent evidence shows that there is also a significant prevalence of IBS in older people. This policy and pathway concentrate on patients aged between 16 and 50. There are other pathways in place to assist in the management of patients with IBD/IBS outside of this specific age group.	No
Social deprivation	It is not clear whether there is a correlation between social deprivation and the incidence of IBD or IBS. The policy and pathway do not differentiate between socio-economic patient groups but provides guidance on the options available to patients based on their clinical presentation.	No
Carers	It is not clear whether there is a correlation between being a carer and the incidence of IBD or IBS. The policy and pathway is intended to provide guidance on the options available to patients based on their clinical presentation alone.	No
Human rights	This policy and pathway does not seek to have a negative impact on an individual's human rights.	No

Equality Impact Assessment Action Plan

Strand	Issue	Action required	How will you measure the outcome/impact	Timescale	Lead