

Guideline

Title: Crohn's Disease Management

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Authors Division:	Medicine		
Departments/Group this Document applies to:	All Clinical Areas; All Clinicians; Patients with suspected or actual Crohn's disease		
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Guideline to be followed by (target staff): All Clinical Areas; All Clinicians; Patients with suspected or actual Crohn's disease			
To be read in conjunction with the following documents:			
Azathioprine Shared Care Trust Guideline Azathiopurine & Mercaptopurine in IBD Full Shared Care.doc			
Are there any eCARE implications? Yes			
CQC Fundamental standards:			
Regulation 9 – person centred care			
Regulation 10 – dignity and respect			
Regulation 11 – Need for consent			
Regulation 12 – Safe care and treatment			
Regulation 13 – Safeguarding service users from abuse and improper treatment			
Regulation 14 – Meeting nutritional and hydration needs			
Regulation 15 – Premises and equipment			
Regulation 17 – Good governance			

Disclaimer – For clinical Guideline only

Since every patient's history is different, and even the most exhaustive sources of information cannot cover every possible eventuality, you should be aware that all information is provided in this document on the basis that the healthcare professionals responsible for patient care will retain full and sole responsibility for decisions relating to patient care; the document is intended to supplement, not substitute for, the expertise and judgment of physicians, pharmacists or other healthcare professionals and should not be taken as an indication of suitability of a particular treatment for a particular individual.

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The ultimate responsibility for the use of the guideline, dosage of drugs and correct following of instructions as well as the interpretation of the published material **lies solely with you** as the medical practitioner.

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1.0 Roles and Responsibilities:

1.1 Policy Statement

The policy has been produced to provide guidance on the clinical management of patients presenting with Crohn's Disease. It has been produced following Professional Consensus. This policy replaces previous policies on the management of Crohn's Disease.

Crohn's disease is a chronic inflammatory disease which predominately affects the gastrointestinal tract. There are currently 115,000 people in the UK with Crohn's disease (NICE, 2019). Crohn's disease can have a significant impact on all aspects of the individual's life.

The onset is of variable age, disease location and behaviour. Crohn's disease runs an unpredictable relapsing and remitting course, with a significant inflammatory component, with a degree of fibrotic, stenosing or perforating disease. The inflammation in Crohn's disease may lead to strictures of the bowel resulting in abdominal pain due to partial blockage. Severe cases may lead to life-threatening complications such as complete blockage or bowel perforation. Crohn's disease is often associated with anal problems such as fissure, tags, abscess, and fistula formation. Between 50% and 70% of individuals with Crohn's disease will undergo surgery within five years of diagnosis.

1.2 Objectives

- Safe and effective treatment of patients
- Continuity of Patient care
- Induce remission

2.0 Implementation and dissemination of document

The document applies to any patient within the Trust with actual or suspected Crohn's Disease.

3.0 Roles and Responsibilities

The consultant in charge of the patient care has overall responsibility for ensuring compliance and adherence with the policy. It is the responsibility of all clinical staff to refer to the policy when caring for a patient with Crohn's Disease.

4.0 Recommendations and Procedures

4.1 Purpose of the Guideline

Patients with suspected Crohn's disease should be referred to a gastroenterologist for appropriate investigation unless there is an immediate surgical indication.

Patients with known Crohn's disease present with a wide variety of symptoms which usually characterise their specific disease anatomy. Symptoms of Crohn's disease are heterogeneous, but commonly include abdominal pain, weight loss and chronic diarrhoea. These symptoms should raise the suspicion of Crohn's disease, especially in young patients.

Systemic symptoms of malaise, anorexia, or fever are common. Further symptoms may include the following:

- Abdominal pain
- Chronic diarrhoea
- iron deficiency and associated anaemia
- extra-intestinal manifestations (joint, eye, skin or hepatobiliary disease)
- Rectal bleeding
- Increased abdominal distension
- Weight loss; anorexia
- Perineal pain

Relapses may be characterised with any of the following: Increased abdominal distension increased abdominal pain, worsening diarrhoea, vomiting, and fistula formation.

4.2 General Management

Ensure throughout the admission process the information and advice provided to the patient, their parent or carer is age appropriate, of the appropriate cognitive & literacy level and meets the cultural and linguistic needs of the patient. Should a translator be required please liaise with the hospital site manager to facilitate (bleep number 1222).

A full history should include detailed questioning about the onset of symptoms, recent travel, food intolerances, medication (including antibiotics and non-steroidal anti-inflammatory drugs), and history of appendectomy. Consider well proven risk factors including smoking, family history, and recent infectious gastroenteritis.

Careful questioning about nocturnal symptoms features of extra intestinal manifestations involving the mouth, eye, skin, or joints, episodes of perianal abscess, or anal fissure is needed.

Extra-intestinal manifestations occur in 35% patients and are more frequent when the colon is involved. Type 1 peripheral arthritis, erythema nodosum, oral aphthous ulcers and episcleritis are associated with disease activity. Pyoderma gangrenosum, uveitis, axial arthropathy and primary sclerosing cholangitis (PSC) are generally independent of disease activity. Metabolic bone disease (osteopenia and osteoporosis) is found in 20-50%.

General examination should include all the following: general wellbeing, pulse rate, blood pressure, temperature, abdominal tenderness or distension, palpable masses, perineal and oral inspection, digital rectal examination. Check for signs of acute and/or chronic inflammatory response, anaemia, fluid depletion, and signs of malnutrition or malabsorption including measurement of body mass index.

- History includes inflammatory bowel disease-specific questions
- Perianal symptoms sample questions to ask
- Consider if there is discharge, determine if mucus, or faecal soiling.
- Assess pain in/near the anus (suggesting an abscess) if so, does the patient have a fever/ lethargy.
- Consider if there sharp anal pain on opening bowels (suggesting a fissure).
- Assess any history of a perianal fistula.

Colonic symptoms

- Diarrhoea and bowel frequency
- Urgency to defecate
- Rectal bleeding

Small bowel symptoms

- Weight loss / malabsorption
- (Post-prandial) abdominal pain
- Diarrhoea
- Vomiting
- Abdominal distension

Foregut symptoms

- Dyspepsia
- Nausea
- Weight loss
- Oesophageal symptoms, e.g. odynophagia, dysphagia.
- Examination to look for weight loss; dehydration; oral ulceration & angular stomatitis; erythema nodosum or pyoderma gangrenosum; arthritis; abdominal mass or fistula; perianal fistula & anal fissure, rectal examination
- Patients may require urgent treatment prior to investigations
- Consider admission if fever or marked abdominal tenderness
- Microbiological testing for infectious diarrhoea including Clostridium difficile toxin is recommended. Additional stool tests may be needed for some patients, especially those who have recently travelled.

Individual with suspected Crohn's disease

- Consider if individual is in transition between paediatric & adult services, liaise with previously attending Trust & attempt to obtain previous investigation reports and any other information of relevance
- Venepuncture & request
- C-reactive Protein (CRP)
- Erythrocyte sedimentation rate (ESR)
- Urea and Electrolytes (U&E)
- Liver Function Tests (LFTS)
- Full Blood Count (FBC)
- Thiopurine methyltransferase: TPMT level (if not previously obtained)
- Stool specimen for microscopy & culture, faecal calprotectin & clostridium difficile (will require two separate specimen collection pots) Serum CRP levels and faecal markers, such as calprotectin can be used to guide therapy and short-term follow-up and to predict clinical relapse. Faecal calprotectin can help to differentiate Crohn's disease from IBS.

A single gold standard for the diagnosis of Crohn's disease is not available. The diagnosis is confirmed by clinical evaluation and a combination of endoscopic, histological, radiological, and/or biochemical investigations.

- Abdominal X-ray (exclude obstruction) and Erect Chest X-ray (exclude obstruction).

If evidence of perforation or obstruction, consult the surgical registrar on call (bleep 1557). Request an urgent CT scan of abdomen.

- Evidence of raised White Cell Count (WCC) and or abdominal mass need urgent ultrasound of abdomen or CT scan to exclude a collection.

Patients with pyrexia or raised WCC or abdominal mass should be started on Intravenous (IV) Amoxicillin 1gram three times daily (tds) and IV Gentamycin once daily (as per protocol) and IV metronidazole 500 mg tds.

If severe IV Piperacillin and Tazobactam 4.5grams tds and IV Metronidazole 500mg tds

For patients with penicillin allergy

Potential allergy with no anaphylaxis – IV Meropenem 1gram tds and IV Metronidazole 500mg tds

If anaphylaxis – discuss with Consultant Microbiologist

- Offer monotherapy with a conventional glucocorticosteroid Oral prednisolone 40 mg daily (od) or Intravenous hydrocortisone 100 mg (qds) to induce remission in people with a first presentation or single inflammatory exacerbation of Crohn's disease in a 12-month period.
- Rectal examination is mandatory to exclude perianal disease and fistulae.

Flexible sigmoidoscopy or colonoscopy. If severe active disease, perform flexible sigmoidoscopy (take 2 biopsies) rather than ileo-colonoscopy, to reduce risk of perforation and request AXR and or small bowel imaging (MRI) this should be organised after d/w gastroenterologist. Cross-sectional imaging (MRI and CT) and trans-abdominal ultrasonography (US) are complementary to endoscopy and offer the opportunity to detect and stage inflammatory, obstructive and fistulising Crohn's disease. Radiation exposure should be considered when selecting techniques. MRI, CT and US have a high accuracy for the diagnosis of small bowel stenosis, penetrating complications and may assist differentiation between predominantly inflammatory and fibrotic strictures.

4.3 Penetrating Crohn's Disease

Crohn's disease can result in disruption of intestinal integrity. This can allow luminal contents to migrate into the abdominal cavity, resulting in an abscess or result in a fistula, namely an abnormal connection between segments of intestine (entero-enteric fistula), or between a segment of intestine and another organ (entero-vesical or entero-vaginal fistula), or between a segment of intestine and the abdominal wall (entero-cutaneous fistula). The latter often arise in the perianal area (perianal Crohn's disease).

The principles of management of fistula are:

- Evaluate whether the originating intestinal loop is inflamed and/or stenosed
- Assess patient's nutritional state
- Plan surgery if appropriate
- Locate the origin and anatomy of the fistula
- Determine which organs are affected
- Exclude local abscess; treat sepsis if present
-

Enterocutaneous fistula

- Multidisciplinary team management required, led by gastroenterologist and colorectal surgeon
- Refer complex disease to specialist centre

Enteroenteric and enterovesical fistulae often requires resective surgery. Surgery is strongly recommended for enteroenteric fistulas if associated with abscess and bowel stricture and if they cause excessive diarrhoea and malabsorption. Screen patients with enterovesical fistula for urinary tract infection.

- Inform Inflammatory bowel disease nurse (extension 86955 / bleep 1807)
- Attempt to facilitate transfer of patient to gastroenterology ward (bed manager bleep 1154)
- Discuss individual and attempt to be transferred to the care of a consultant gastroenterologist and/or colorectal surgeon within 24 hours of admission.
- All patients admitted need to be weighed and their nutritional needs assessed, refer to dietician as need dictates.
- Commence stool chart to enable monitoring
- Daily Harvey-Bradshaw Index (HBI) assessment and documentation to enable effective monitoring of Crohn's disease activity (Appendix 1). Consider any communication difficulties, that could effect the scores.
- Patients with Crohn's disease and their family members may require specific information sheets, refer to www.crohnsandcolitis.org.uk for printable versions.

[http://s3-eu-west-](http://s3-eu-west-1.amazonaws.com/files.crohnsandcolitis.org.uk/Publications/crohns-disease.pdf)

[1.amazonaws.com/files.crohnsandcolitis.org.uk/Publications/crohns-disease.pdf](http://s3-eu-west-1.amazonaws.com/files.crohnsandcolitis.org.uk/Publications/crohns-disease.pdf)

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4.4 Inducing remission in Crohn's disease

- In people with one or more distal ileal, ileocaecal or right sided colonic disease who decline, cannot tolerate or conventional corticosteroid therapy is contraindicated consider budesonide for a first presentation or single inflammatory exacerbation in a 12-month period. (Explain to individual this treatment is less effective than a conventional

corticosteroid but may have fewer associated side effects. Do not offer for severe presentations).

- Azathioprine, mercaptopurine or methotrexate are not to be offered as monotherapy to induce remission.

Exclusive Enteral Nutrition has not demonstrated in research to be an effective method for inducing remission in adults.

Mesalazine orally has no or very little efficacy in maintaining clinical remission in Crohn's disease.

Add on treatments

- Consider adding azathioprine or mercaptopurine to a conventional glucocorticosteroid or budesonide to induce remission of Crohn's if:
 - There are two or more inflammatory exacerbations in a 12-month period or the glucocorticosteroid dose cannot be gradually decreased effectively.
- Consider adding methotrexate to a conventional glucocorticosteroid or budesonide to induce remission of Crohn's in patients who cannot tolerate azathioprine or mercaptopurine, or in whom TPMT activity is deficient.
 - There are two or more inflammatory exacerbations in a 12-month period or the glucocorticosteroid dose cannot be gradually decreased effectively.

[Azathiopurine & Mercaptopurine in IBD Full Shared Care.doc](#)

4.5 Crohn's disease patients with evidence of obstruction

Present with abdominal pain, distension, nausea and vomiting

- Abdominal X-ray looking for small or large bowel dilatation
- Ask for urgent surgical consultation (surgical registrar on call)
- Keep Nil by Mouth
- Nasogastric (NG) tube to decompress the stomach
- IV fluid replacement (at least the same as NG aspirate plus 10 mls/hour)
- Start IV antibiotics as in section 4.2
- Start IV Steroids Hydrocortisone 100mg qds
- Discuss with gastroenterologist within 24 hours

4.6 Crohn's disease patients with relapse of symptoms

Present with one or more of the following:

- Abdominal pains
- Temperature > 37.5°C
- Increased bowel frequency (usually >6 x day with urgency and nocturnal symptoms)
- Other extra-intestinal manifestations
- General treatment management
- IV hydrocortisone 100 mg qds (if vomiting) or oral prednisolone 40 mg od

- Increase oral 5-ASA to maximum dose
- Oral metronidazole 400 mg tds if perianal or colonic disease
- Consider elemental/polymeric diet if symptoms of subacute obstruction or known small bowel disease-refer to dietician.
- Start IV antibiotics as in section 4.2
 - If there is no response the patient should be referred to a gastroenterologist and as IV infliximab (5 mg/kg) is needed as per NICE criteria if no clinical response after 7 days. Patients with objective evidence of active disease refractory to corticosteroids should be treated with an anti-TNF based strategy, although surgical options should also be considered and discussed at an early stage
- Severe disease
- Steroid-refractory disease
- Likelihood severe disease e.g. extensive small bowel disease; perianal disease
- Avoid side effects of alternative treatment (steroids, surgery)
- Lack of efficacy/contraindication/intolerance of classical immunomodulation.

Risk factors for a poor disease outcome

The course of Crohn's disease may be predicted by clinical factors at diagnosis and/or endoscopic findings. This should be taken into account when determining a therapeutic strategy. The risk factors for a poor disease outcome include:

- Complex perianal disease
- Colonic resection
- At least 2 small bowel resections
- Definitive stoma within 5y of diagnosis
- Smoking (smoking increases need for steroids, immunosuppressant's and surgery. (recommend a smoking cessation program)
- Extensive small bowel disease
- Onset < 40y
- Corticosteroids at diagnosis
- Perianal / rectal disease
- Stricturing disease
- >5kg weight loss pre-diagnosis
- Deep and extensive colonic ulceration
- Steroid-dependency

Consider potential disease modifying therapy in those with at least two of the above factors In general, antibiotics are only appropriate for septic complications, bacterial overgrowth, post-operative prophylaxis or perianal disease.

- Metronidazole can induce a response or even remission in colonic Crohn's disease, but not in small bowel disease; although poorly tolerated long term.
- Ciprofloxacin has similar efficacy in active luminal disease as mesalazine.
- Ciprofloxacin with metronidazole can induce remission.
- Metronidazole / Ciprofloxacin use in perianal disease has some supportive evidence, however they rarely induce complete healing; exacerbations often occur when discontinued. They are usually used as adjunct to thiopurines and anti-TNF therapy in perianal Crohn's disease.

- Peripheral neuropathy limits the long-term use of metronidazole and can persist in some patients. Tendon inflammation and damage can occur due to ciprofloxacin.
- National Formulary should be consulted to review adverse drug reactions and drug interactions.

Surgery and the Prevention of relapse post-surgery.

- Surgical resection is widely utilised for fibrotic small bowel disease causing obstructive symptoms and for active disease after failure of medical therapy (which typically would have included biological therapy. Complex entero-enteric and entero-colic fistulation is occasionally also dealt with surgically. There is additionally reasonable evidence for primary surgical resection of newly diagnosed inflammatory ileo-caecal disease compared with step-up/top-down medical therapy.
- To maintain remission in people with ileocolonic Crohn's disease, who have had complete macroscopic resection within the last 3 months. Consider thiopurine with up to 3 months postoperative metronidazole 20mg/kg/d.
- Early post-operative IBD MDT discussion to review post-operative management.
- Ileocolonoscopy assessment at 6 months postoperatively.

In patients with an aggressive disease course or considered to be high risk with poor prognostic factors, the early introduction of biologics should be considered.

Biological therapy

Infliximab and Azathioprine is superior to Infliximab monotherapy. The importance of combination therapy is not as strong as in studies with adalimumab. However, combination is slightly better than adalimumab monotherapy for induction of remission.

Anti- TNF therapy is indicated for the treatment of Inflammatory Bowel Disease (IBD) in the following circumstances:

Adult Crohn's Disease (CD):

- Treatment of severe, active CD, in patients who have not responded despite a full and adequate course of therapy with a corticosteroid and/or immunosuppressant; or who are intolerant to or have contraindications for such therapies.
- Treatment of fistulating, active CD, in patients who have not responded despite a full and adequate course of therapy with conventional treatment (including antibiotics, drainage and immunosuppressive therapy).
- Patients for whom surgery is inappropriate or undesirable such as diffuse disease and/or risk of short bowel syndrome.

All currently available anti-TNF therapies appear to have similar efficacy in luminal Crohn's disease and similar adverse-event profiles, so the choice depends on availability, route of delivery, patient preference, and cost. Adalimumab and Infliximab are licensed for Crohn's disease.

- 160 mg Adalimumab is given subcutaneously at week 0, 80 mg at week 2, then 40 mg EOW

Infliximab in severe active CD

5mg/kg IV infusion is given over 2 hours at 0, 2 and 6 weeks in patients who have fulfilled the above criteria. In patients who respond, treatment should then be continued with infusions every 8 weeks, unless treatment fails (including the need for surgery) for up to a year and then stop treatment pending further out-patient review. It is important the decision is discussed in MDT where risks v benefits can be considered. Available data does not support Infliximab treatment in patients not responding within 10 weeks of the initial infusion.

- Planned course of treatment: repeat infusions of 5mg/kg every 8 weeks depending on response.
- While the majority of patients should maintain remission on the above regimen, patients who previously had a good response but who now deteriorate before their next maintenance dose, may need a reduction in the interval between infusions or an increase in dose to 10mg/kg. This is likely to be more cost effective than initiation of Adalimumab. If remission has been achieved with the combination of anti-TNF therapy and thiopurines in treatment naïve patients, maintenance with the same regimen is recommended. Thiopurine may be an option as monotherapy in selected patients who have achieved sustained remission on combination therapy. If remission has been achieved with anti-TNF monotherapy, maintenance with anti-TNF monotherapy is appropriate.

Infliximab in fistulating, active CD

5mg/kg I/V infusion is given over 2 hours at 0, 2 and 6 weeks. In patients who respond, treatment should then be continued every 8 weeks, unless treatment fails (including the need for surgery) for up to a year and then stop, pending a further out-patient review.

- If a patient does not respond after 3 doses, no further treatment with Infliximab should be given. Primary lack of response to an anti TNF based strategy should be determined within 12 weeks
- Careful consideration should be given to appropriate drainage of complex fistulae prior to Infliximab administration.

Vedolizumab has been demonstrated to be effective in inducing remission in Crohn's disease. It can be used in both anti-TNF naïve patients and those where anti-TNF therapy has failed.

300mg I/V infusion is given over 30 minutes at 0, 2 and 6 weeks. In patients who do not respond, a week 10 infusion can be administered on advice of the Consultant Gastroenterologist. Remission rates are better for TNF naïve patients. Treatment should then be continued every 8 weeks, unless treatment fails (including the need for surgery) for up to a year and then stop, pending a further out-patient review. It is important the decision is discussed in MDT where risks v benefits can be considered.

Ustekinumab can be used for the induction and maintenance of remission in Crohn's disease. Both anti-TNF naïve patients and those where anti-TNF therapy has failed.

Approximately 6mg/kg I/V infusion is given over 1 hour at week zero-from there a 90mg subcutaneous dose 8 weekly.

Studies comparing Ustekinumab and Vedolizumab in patients who have failed anti-TNF, suggest no difference in efficacy. The choice should be made on an individual basis.

Considerations should include, patient preference, cost, adherence, safety data, speed of

response. The potential for surgery as an alternative to further drug therapy should be considered.

5.0 Statement of evidence/references

Statement of evidence:

Professional Consensus

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5.0 Governance

5.1 Document review history

Version	Date	Name	Reason
1.0	6/2003	Dr Lanzon-Miller Dr Madhotra	New Policy
2.0	10/2007	Dr Madhotra	Update of policy
3.0	02/2009	Dr Madhotra	Minor changes
4.0	04/2011	Dr MacFaul	Reviewed and updated. Changes to Antibiotic use. New policy format
5.0	07/2015	Dr MacFaul	Formatting changes
	12/2015	Dr Madhotra	Update of references.
5.1	06/2020	Lianne Lewis	Update and amendments

5.2 Consultation History

Stakeholder Name	Area of Expertise	Date Sent	Date Received	Comments	Changes Made
Dr Madhotra	Consultant Gastroenterologist	3/2011	3/2011	Suggested add in CT scan	CT scan added
Dr Macfaul	Consultant Gastroenterologist	4/2011	4/2011	Minor amendments	Added
Dr Rangunathan	Consultant Microbiologist	4/2011	4/2011	Update of antibiotics	Update of antibiotics
Quynh-anh Nguyen	Pharmacist	4/2011	4/2011	Review of antibiotics	Update of antibiotics
Dr MacFaul	Consultant		6/2020	Update and amendments	Update and amendments
Lianne Lewis	ANP		6/2020	Update and amendments	Update and amendments

5.3 Audit and monitoring

Document Audit and Monitoring Table	
Monitoring requirements:	a) Audit of patients b) Staff feedback
Monitoring Method:	a) Report b) Incident forms / verbal feedback / minutes of meetings
Monitoring prepared by:	a) & b) Member of staff designated by Consultant Gastroenterologist
Monitoring presented to:	a)& b) Directorate of Medicine Audit Meeting
Frequency of presentation:	a) & b) Bi-annually

5.4 Equality Impact Assessment

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As part of its development, this Guideline and its impact on equality has been reviewed. The purpose of the assessment is to minimise and if possible remove any disproportionate impact on the grounds of race, gender, disability, age, sexual orientation, religion or belief, pregnancy and maternity, gender reassignment or marriage and civil partnership. No detriment was identified. Equality Impact assessments will show any future actions required to overcome any identified barriers or discriminatory practice.

Equality Impact Assessment			
Division	Medicine	Department	IBD - Gastroenterology
Person completing the EqIA	Lianne Lewis	Contact No.	
Others involved:		Date of assessment:	
Existing policy/service	Yes	New policy/service	
Will patients, carers, the public or staff be affected by the policy/service?			
		Yes	
If staff, how many/which groups will be affected?			
		community midwives, phlebotomists, all staff	
Protected characteristic	Any impact?	Comments	
Age	YES NO	Positive impact as the policy aims to recognise diversity, promote inclusion and fair treatment for patients and staff	
Disability	YES NO		
Gender reassignment	YES NO		
Marriage and civil partnership	YES NO		
Pregnancy and maternity	YES NO		
Race	YES NO		
Religion or belief	YES NO		
Sex	YES NO		
Sexual orientation	YES NO		
What consultation method(s) have you carried out?			
focus groups, face-to-face meetings, PRG, etc			
How are the changes/amendments to the policies/services communicated?			
email, meetings, intranet post, etc			
What future actions need to be taken to overcome any barriers or discrimination?			
What?	Who will lead this?	Date of completion	Resources needed
Review date of EqIA	July 2020		

Appendix 1

Rutgeerts' score	Endoscopic description of findings
i0	no lesions
i1	≤5 aphthous ulcers
i2	>5 aphthous ulcers with normal intervening mucosa, skip areas of larger lesions, or lesions confined to ileocolonic anastomosis
i3	diffuse aphthous ileitis with diffusely inflamed mucosa
i4	diffuse inflammation with larger ulcers, nodules and/or narrowing

Adapted From Rutgeerts et al.⁷