Guidance for the Prevention and Management of Constipation in Adults

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Presented for discussion, approval and ratification to

| Area Clinical Effectiveness (ACE) | May 2018 |

Change History

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A previous guidance document was published jointly by Dudley B & C and Dudley South Primary Care Trusts in 2002. It was widely distributed to Community Nursing Teams and training was delivered by the Continence Advisory Team. Updated guidance, from the Royal College of Nursing (RCN), on bowel care together with a growing body of evidence to support the management and treatment of constipation required the existing CCG guidance to be reviewed and updated. Formulary changes were agreed by the Area Medicines Management Committee (AMMC) to accommodate the needs of inpatient care, palliative care and patients treated by primary care clinicians. Guidance was reviewed in 2011 and updated following publication of NICE Technology Appraisal 211 Dec 2010 – Prucalopride for the treatment of chronic constipation in women.

Constipation can be a distressing symptom, severity can vary from slight, causing no disruption to daily life, to severe, affecting physical, psychological and social well-being. Overcoming communication barriers associated with open discussion of bowel habits and other sensitive Gastro Intestinal related symptoms is a skill required and one to be developed in all care settings.

Related CCG Documents:
Guidelines for promotion of urinary continence in females and of lower urinary tract Symptoms (LUTS) in males
http://www.dudleyformulary.nhs.uk/page/20/guidelines

Guidelines for the drug treatment of pain in primary care.
http://www.dudley.nhs.uk/Formulary/Index.aspx?id=8

Medication Review – Best Practice Guidelines.
http://www.dudley.nhs.uk/Formulary/Index.aspx?id=8

Relevant National Documents:

NICE Technology Appraisal Guidance 211 - Prucalopride for the treatment of chronic constipation in women. Published 15/12/2010.
NICE Technology Appraisal Guidance 318 - Lubiprostone for treating chronic idiopathic constipation. Published 23/07/2014.
NICE technology Appraisal guidance 345 - Naloxegol for treating opioid-induced constipation. Published July 2015.

To be reviewed in 3 years by CCG and Community Nursing Teams or sooner if required.

**Scope:**
This guidance does **not** apply to children or people below the age of 16 years of age. NICE CG 99 Constipation in Children and Young People should be used in this age group. [http://guidance.nice.org.uk/CYG99](http://guidance.nice.org.uk/CYG99)

**Clinical Audit:**

It is recommended that these Guidelines be audited within two years of date of approval. Prevention and treatment guidelines through Community Nursing Teams and formulary drug choices in GP practice prescribing with the assistance of Practice based Pharmacist team.

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1. Introduction

Constipation can be a symptom of many diseases and disorders. The management of constipation is a challenge for all healthcare professionals. The importance of educating and training all members of the healthcare team, including care assistants in residential and nursing homes, in the management of bowel care is important. An evidence based approach using a risk assessment tool, management of constipation flow chart, preventative and treatment guidelines should facilitate good practice across Dudley.

If left untreated constipation may lead to rectal loading/faecal impaction, or even faecal incontinence as a result of the impacted bowel.

Constipation requires immediate assessment if accompanied by symptoms of undiagnosed rectal bleeding, weight loss, abdominal pain and vomiting as may be indicative of colorectal cancer and is advisable to seek guidance.

A definition of constipation:

Bowel habits vary from one person to another. The British National Formulary suggests “the passage of hard stools less frequently than the patient’s own normal pattern”. The definition of constipation differs from patients and perspectives.

A consensual definition has been developed based on quantitative criteria assessing defecation difficulties and stool frequency (Rome II criteria)\(^2\). According to this definition, constipation is diagnosed when at least two out of the following six criteria are present for at least 12 weeks in the preceding 12 months.

- Straining during at least 25% of bowel movements
- Pellet-like or hard stools for at least 25% of bowel movements
- Sensation of incomplete evacuation for at least 25% of bowel movements
- Sensation of anal blockage for at least 25% of bowel movements
- Using manual manoeuvres (including digital evacuation or pressure on the perineum) to facilitate more than 25% of bowel movements
- Having fewer than three bowel movements per week

Applying this standardised definition and using quantitative criteria should become a necessary first step in the management of patients that would help in guiding treatment and monitoring progress.

However, in summary constipation can most easily be defined as a variation in an individual’s normal bowel function. People’s perceptions of constipation vary greatly and normal bowel function may involve defecation three times daily or once every three days, but diagnosis may take place when there is a marked reduction in the amount of stools and/or reduced frequency of defecation.
2. Types of Constipation

**Chronic** - Long standing constipation either because of medication or long term condition.

**Acute** - Constipation has suddenly occurred either because of holiday, antibiotic therapy, surgery, pregnancy, inadequate fluid and/or fibre intake. This can be changed through lifestyle modification.

**Impacted** - The constipated stool is lodged in the colon (descending, transverse, ascending) requires oral and rectal medication to alleviate the problem.

**Idiopathic** – Idiopathic constipation is when the bowel is underactive and can be termed functional constipation. The condition tends to start in childhood and persists throughout life and there is no known cause. Specialist advice is recommended.

3. Further Investigation & Specialist Treatment

Referral for further investigation is essential if patients present with any of the following ‘red flag’ symptoms.

- Change in bowel habit from own normal pattern for more than 6 weeks.
- Undiagnosed persistent rectal bleeding without anal symptoms.
- Abdominal pain.
- Passing mucus or blood per rectum.
- Unintentional anorexia and weight loss.
- A family history of bowel or ovarian cancer.
- Severe, persistent constipation that is unresponsive to treatment
- Other symptoms iron deficiency anaemia, fever or nocturnal symptoms.

In addition the early detection of colorectal cancer in primary care patients over 45 years needs to be considered.

4. Who is at Risk of Suffering from Constipation?

People at risk of constipation include:

- Those taking more than five prescribed medications.
- Those taking drugs with antimuscarinic (anticholinergic) effects - tricyclic/SSRI/SNRI antidepressants, orphenadrine, procyclidine, opioid analgesics, iron, nifedipine/verapamil, antacids, Non-Steroidal Anti-Inflammatory Drugs (NSAIDs), antihistamines – especially older sedating antihistamines e.g. chlorphenamine, promethazine and cyclizine; antipsychotics and 5HT₃ antagonists e.g. ondansetron.
- Frail elderly or immobile younger adults.
- Nursing home or care home residents.
- Patients with Parkinson’s disease, multiple sclerosis, spinal cord disease or injury, stroke, diabetes mellitus, chronic renal failure, clinical dehydration.
• Patients with hypothyroidism, uraemia, hypocalcaemia or hypocalcaemia.
• Patients with learning disabilities or cognitive impairment, e.g. dementia, Alzheimer’s.
• Terminally ill or palliative care patients.
• Post-operative patients.
• Pregnant or post-natal women.
• Lack of teeth or poorly fitting dentures, swallowing difficulties.
• In addition patients with Coronary Heart Disease with constipation are at a higher risk of cardiovascular events if straining on the toilet.
• Confused and/or depressed patients may ignore the sensation of stool in the rectum, leading to constipation.

5. Causes of Constipation

There are a number of factors that can lead to, or cause, constipation:

• A diet that is insufficient in or lacks adequate fibre.
• Insufficient fluid intake.
• Insufficient physical activity.
• Organically derived delay in colonic transit time.
• Evacuation difficulties caused by hard impacted stools or nerve damage.
• Anorectal conditions e.g., haemorrhoids or anal fissure, rectal prolapse, rectocele, anismus (contraction rather than relaxation of the anal sphincter), megacolon or megarectum.
• Bowel disorders such as inflammatory bowel disorder (e.g. Crohn’s, Ulcerative Colitis etc.), Irritable Bowel Syndrome, diverticular disease and carcinoma.
• Coeliac Disease.
• Surgical or diagnostic procedures, post-operative constipation.
• Habit or routine such as ignoring the desire to open bowels.
• Polypharmacy or multiple medications.
• Spinal injury/disorders.
• Urinary problems.

6. Management of Constipation in Adults

Clinicians and trained allied health care professionals should use the ‘Risk Assessment Tool’ (Appendix 1, Page 26 to guide them in management of patients presenting with constipation. Management, to include dietary, lifestyle advice and treatment with laxatives or further referral should then be offered. For some patients, chronic constipation can have a substantial impact on their quality of life. High dose laxatives may not be effective and other invasive procedures may need to be considered. The introduction of prucalopride, linaclonide and lubiprostone could provide an alternative
to invasive procedures. Use of these drugs is recommended in-line with NICE TAG via referral to secondary care.

**Digital Rectal Examination (DRE)**

DRE is the insertion of a lubricated, gloved finger into the anal canal and then rotated gently in a clockwise motion in order to ascertain the type of stool in the anal canal. It can initiate stimulation of the bowel and thus elimination may occur naturally. Patients who are experiencing constipation (who have not been able to fully eliminate for at least 5 days) may require DRE. They need to be referred to the Community Nursing Team to assess the anal canal and see if medication is required and to further assist patient management.

**Competence to perform this technique must be demonstrated before undertaking as per Royal College of Nursing (RCN) Guidelines. Full training and assessment is provided by Dudley Group NHS Foundation Trust (DGNHSFT) Continence Service.**

Management of Adult Constipation for Nurses trained in DRE - Appendix 8 is included for completeness as a reference for nurses competent to use DRE from the previous 2004 Guidelines.

DRE must not be embarked upon unless covered by further training.

**Additional Tools to support management:**

Ideas to increase your fibre intake - Appendix 2, Page 26.
Fluid Intake Matrix – Appendix 3, Page 27.
Bowel Habit Diaries – Appendix 4, Page 28 & 29.
Food and Fluid Record Diary – Appendix 5, Page 30.
Management of Constipation in Palliative Care – Appendix 6, Page 31.
Bristol Stool Chart3 – Appendix 7, Page 32.
Management of Adult Constipation by Nurses trained in DRE – Appendix 8, Page 31.
Secondary care agreement form for prescribing Prucalopride – Appendix 9, Page 32.
Secondary care agreement form for prescribing Naloxegol – Appendix 10, Page 33.

Management to consist of (where applicable):

- Standard lifestyle advice is to increase fluid, fibre and physical activity. It is not always possible to achieve this in frail elderly and immobile patients however where possible consider passive exercises, walking short distances and standing up from chair to relieve pressure areas.
- Review dietary fibre intake using the food record diary (Appendix 5) and the fluid intake matrix (Appendix 3) and advise accordingly. Use ideas regarding fibre intake (Appendix 2) and monitor outcome using the bowel habit diaries (Appendix 4) together with food record diary. If patient is under-weight consider involving dietitian for advice regarding nutritional supplements with added dietary fibre. Ask family/carers for support e.g. to buy favourite fruit etc.
- Frail elderly patients or those with learning disabilities may require the assistance of a relative or carer to manage their fibre and fluid intake and complete a bowel diary on their behalf. Guidance on ensuring patients/clients and carers are fully involved in a three way dialogue with the health care professional must be followed and that wishes and the advocacy role is respected. A bowel habit diary for use by carers can be found at appendix 4.
• Review medication – examples of medications that may cause or aggravate constipation, include sedatives, analgesics, anticholinergics etc. Seek practice based pharmacist input for assistance with medication review. See Medication Review Guidelines.

• Look at toileting aids to ensure stability and correct position on toilet - involve occupational therapist, use of raised toilet seats (can the person sit with their feet firmly on the floor, or is a step required), toilet frames to provide stability. Seek advice for Continence Service.

• Discuss with patient what their normal triggers are for going to the toilet, such as first cup of coffee, or after breakfast, and help them to maintain or develop a routine where possible.

• Management of constipation may require a multi-disciplinary approach with the physiotherapist, occupational therapist, dietitian, continence adviser, GP, pharmacist, care assistant etc.

• The use of laxatives may be a necessary part of patient’s treatment management plans.

• On-going monitoring should be a feature of good clinical care. Once effective management is established patients should be able, and be guided, to take responsibility for self-management by making adjustments to lifestyle or laxative use as appropriate.
7. **Treatment of Constipation in Adults Flowchart**

**General Management**

Patient presents with suspected Constipation

**Alarm Signs:**
- Rectal Bleeding
- Severe abdominal pain
- Passing Mucous PR
- Weight Loss
- Anorexia
- Tenesmus (painful and ineffectual straining)
- Iron deficient anaemia
- Fever
- Nocturnal symptoms

Discuss with GP, Treat underlying cause, Consider Referral

YES

**Use risk assessment tool. Appendix 1**

Make changes towards a healthier lifestyle

**Medication review**
- Fluid intake – see appendix 4
- Nutrition – see appendices 2,3,5,6
- Dietary fibre (18-35g a day) – see appendices 2&3
- Daily Physical Activity

Assess for type of constipation

- Acute
- Chronic
- Faecal Impaction
- Idiopathic

Consider laxative usage - see prescribing guidance table

**Review regularly**
8. Formulary Drug Choices

Bulk Forming Laxatives:

These laxatives are effective in simple chronic constipation arising from a low fibre, low fluid diet. They increase the faecal bulk by directly increasing the volume of faecal material, which stimulates peristalsis.

Formulary Choice – Isphaghula husk.

Contraindications:

- Intestinal obstruction.
- Swallowing difficulties
- Atonic colon.
- Faecal impaction.
- Chronic constipation (duration of more than 6 months)

Side effects:

- Flatulence and abdominal distension.

Prescribing points: See also chart on page 19.

- May take up to 3 days to have an effect.
- Must be mixed with water and taken as a drink as soon as prepared. Additional fluid should be drunk throughout the day. (May not be suitable for frail elderly people).
- Not to be taken before going to bed in order to reduce the risk of obstruction.
- May reduce appetite.
- Not recommended as first-line treatment for patients taking medication that causes constipation.

Stimulant laxatives and rectal preparations:

Stimulant laxatives increase intestinal motility and work quickly.

Formulary Choices –

- Senna (1st line)
- Docusate Sodium (2nd line)
- Bisacodyl (3rd line)
- Glycerin Suppositories, Sodium Picosulfate (on specialist recommendation only)
Co-danthrusate is limited to the management of analgesic induced constipation in terminally ill patients and should only be prescribed in consultation with a Specialist. These drugs have limited availability and can be expensive.

**Contraindications:**

- Abdominal obstruction.
- Acute surgical abdominal conditions.
- Acute inflammatory bowel disease.
- Severe dehydration.

**Side effects:**

- Abdominal cramps.
- Danthron preparations may colour urine red.
- Excessive use can cause diarrhoea and related effects such as hypokalaemia.

**Prescribing points:** See also chart on pages 19-21.

- The laxative effect of stimulant laxative is seen within 8-12 hours so they should be taken at night to produce a morning bowel movement.
- Chronic use should be avoided as can cause fluid and electrolyte imbalance and colonic atony.
- Bisacodyl suppositories may cause some local irritation to the rectum.
- Docusate sodium probably acts both as a stimulant and as a softening agent.

**Osmotic laxatives**

Macrogols and Lactulose retain fluid in the large intestine by osmosis, causing intestinal distension and eventual peristalsis.

**Formulary Choices:**

- Macrogol 3350 (Cosmocol or Laxido) 1st line. (Cosmocol is the preferred formulary choice).
- Sodium Citrate Rectal.
- Lactulose (only when other laxatives cannot be tolerated and not routinely).
Contraindications:
- Intestinal obstruction
- Lactulose is contraindicated in galactosaemia

Side effects:
- Cramps, nausea, flatulence and general abdominal discomfort.

Prescribing points: (See also chart on pages 19-21)
- Cosmocol and Laxido include electrolytes to help protect against loss of potassium or sodium.
- Lactulose is best administered with either water or fruit juice and requires regular dosing. It may take up to 3 days to have any effect and therefore is not suitable for rapid relief.
- Can lead to dehydration if inadequate fluid intake (dehydration can manifest as confusion and renal impairment especially in the elderly).

Faecal Softeners:
These products assist mucous in the lubrication of faeces to promote easier passage as well as softening faeces. Docusate sodium also possesses some stimulant activity. Softeners should be used to avoid straining during defecation (e.g. after myocardial infarction, surgery or in hernia or anorectal problems).

Formulary Choices:
- Docusate Sodium capsules 100mg & liquid 50mg/5ml only (1st line).

Contraindications:
- Oral Docusate sodium should not be prescribed in intestinal obstruction or clients with nausea, vomiting and abdominal pain.

Side effects:
- Oral docusate sodium may cause nausea, anorexia and cramp.
- Increased absorption occurs when oral Docusate sodium is taken alone and not within an hour of other drugs.

Prescribing points:
- Adequate water should be consumed at the same time.
- A laxative effect is seen in 1-2 days.
- Docusate liquid has a bitter taste.
Arachis oil enemas are not recommended in constipation due to limited evidence, high cost and the risk in peanut allergy.

Phosphates (Rectal)

- Phosphate enemas are no longer recommended in constipation, particularly in the frail elderly, renal impairment and dehydration due to limited evidence and equally effective treatments causing less side effects are available. Use in faecal impaction would be on specialist advice after exhausting treatment with first line measures as described in the table below.

Bowel Cleansing Solutions

Formulary Choice:

- Sodium Picosulfate (On specialist recommendation only).

Prucalopride (NICE Technology Appraisal 211 Dec 2010)

Prucalopride is a drug licensed for the treatment of chronic constipation in women. It is a first in class dihydrobenzofuran carboxamide derivative, which acts on a selective serotonin (5HT4) receptor agonist. This action results in increased acetylcholine release in the GI tract, which in turn stimulates colonic motility thereby restoring bowel function. Prucalopride is structurally different from other non-selective serotonergic prokinetic agents such as cisapride (now withdrawn).

Contraindications

- Due to mechanism of action, the drug is contraindicated in patients with intestinal perforation, obstruction or severe inflammatory conditions of the gastrointestinal tract
- Patients with drug induced constipation, renal failure, liver failure, cardiovascular disease and constipation caused by endocrine, metabolic or neurological disorders were excluded from clinical trials.

Side effects

- Headache, abdominal pain, nausea or diarrhoea.

Interactions

- See current BNF. Should be used with extreme caution with amiodarone, clarithromycin, erythromycin and haloperidol and any other known drugs which prolong the QTc interval.

Prescribing points

- For consultant initiation only. Clear guidance in NICE TA 211. See proforma at appendix 9. To only be prescribed by clinicians with
experience in treating constipation. In the first instance, patients in Dudley should be referred to secondary care for full assessment and monitored treatment. The step approach in these guidelines to be taken and referral to the continence service for shared care and on-going monitoring if treatment with prucalopride is effective.

- Considered for women with chronic constipation who have failed to obtain adequate relief from at least six months of treatment with laxatives, from at least two different classes, at maximally tolerated doses and in whom invasive treatment for constipation is being considered. All other laxatives should be stopped prior to starting treatment with prucalopride.

- Treatment should be reconsidered if there is a lack of effect after 4 weeks.

- Monitoring for on-going effective treatment is required.

**Lubiprostone (NICE Technology Appraisal 318 July 2014)**

Lubiprostone is a bicyclic fatty acid and a locally acting chloride channel activator that enhances the secretion of chloride rich intestinal fluid without altering electrolyte concentration in the serum.

**Contraindications**

- Lubiprostone should not be used in patients with a known or suspected mechanical gastrointestinal obstruction.

**Side effects**

- The summary of product characteristics lists the following adverse reactions: nausea, palpitations, diarrhoea, abdominal distension, flatulence, abdominal discomfort, abdominal pain, indigestion, oedema (including peripheral), chest discomfort, headache, dizziness, dyspnoea, hyperhidrosis and hot flushes.

- For full details of adverse reactions and contraindications, see the summary of product characteristics.

**Interactions**

- See current BNF and summary of product characteristics. Based upon the results of in vitro human microsome studies, there is low likelihood of drug–drug interactions.

**Prescribing Points**

- Lubiprostone is recommended as an option for treating chronic idiopathic constipation, that is, for adults in whom treatment with at least 2 laxatives from different classes, at the highest tolerated recommended doses for at least 6 months, has failed to provide adequate relief and for whom invasive treatment for constipation is being considered.

- If treatment with lubiprostone is not effective after 2 weeks, the person should be re-examined and the benefit of continuing treatment reconsidered.

- Lubiprostone should only be prescribed by a clinician with experience of treating chronic idiopathic constipation, who has carefully reviewed the
person's previous courses of laxative treatments.

- The efficacy of lubiprostone beyond 4 weeks has not been demonstrated in placebo-controlled trials. Therefore; a course of treatment with lubiprostone should not exceed 4 weeks and is restricted for specialist use only.
- Lubiprostone has black triangle status (▼) and is subject to additional monitoring requirements. All suspected adverse effects should be reported via the yellow card system [https://yellowcard.mhra.gov.uk/](https://yellowcard.mhra.gov.uk/)

### Naloxegol (NICE Technology Appraisal 345 July 2015)

Naloxegol is a form of naloxol which has been pegylated (that is, attached to a molecule of polyethylene glycol, or PEG). In this form, it selectively antagonises peripheral opioid receptors to relieve constipation. It has a marketing authorisation for treating opioid-induced constipation (OIC) in adults whose constipation has had an inadequate response to laxative(s).

#### Contraindications

- Gastrointestinal obstruction - Patients with known or suspected gastrointestinal (GI) obstruction or in patients at increased risk of recurrent obstruction, due to the potential for gastrointestinal perforation. See SPC for further information.
- Patients with underlying cancer who are at heightened risk of GI perforation, such as those with:
  - underlying malignancies of gastrointestinal tract or peritoneum
  - recurrent or advanced ovarian cancer
  - vascular endothelial growth factor (VEGF) inhibitor treatment

#### Side-effects

- The most commonly reported adverse reactions to naloxegol are abdominal pain, diarrhoea, nausea, headache and flatulence. The majority of gastrointestinal adverse reactions are graded as mild to moderate, occur early in treatment and resolve with continued treatment. For full details of adverse reactions and contraindications, see the SPC.

#### Interactions

- See current BNF and summary of product characteristics. Concomitant use with strong CYP3A4 inhibitors is contraindicated i.e. clarithromycin, telithromycin, nefazodone, itraconazole, ketoconazole, grapefruit (if consumed in large quantities).
- A dose adjustment of naloxegol is recommended when co-administered with diltiazem and other moderate CYP3A4 inhibitors.
- Naloxegol is not recommended in patients who are taking strong CYP3A4 inducers i.e. rifampicin (this list is not exhaustive).

#### Prescribing Points:

- Naloxegol is used for the management of opioid induced constipation in adults whose constipation has not adequately responded to laxatives in line with NICE TA 345.
- An inadequate response is defined as opioid-induced constipation symptoms of at least moderate severity in at least 1 of the 4 stool symptom domains (that is, incomplete bowel movement, hard stools, straining or false alarms) while taking at least 1 laxative class for at least 4 days during the prior 2 weeks.
- When naloxegol therapy is initiated, it is recommended that all currently used maintenance laxative therapy should be halted, until clinical effect of naloxegol is determined.
- It is recommended that Naloxegol is taken in the morning, for patient convenience to avoid bowel movements in the middle of the night.
- Naloxegol should be taken on an empty stomach at least 30 minutes prior to the first meal of the day or 2 hours after the first meal of the day.
- For patients who are unable to swallow the tablet whole, the Naloxegol (Moventig®) tablet can be crushed to a powder and mixed in half a glass of water (120 ml) and drunk immediately. The glass should be rinsed with a further half glass of water (120 ml) and the contents drunk. The mixture can also be administered via a nasogastric tube (CH8 or greater). It is important to flush the nasogastric tube through with water after administration of the mixture.
- Naloxegol has black triangle status (▼) and is subject to additional monitoring requirements. All suspected adverse effects should be reported via the yellow card system https://yellowcard.mhra.gov.uk/

Management of Constipation in Pregnancy:

If dietary and lifestyle changes (see above) fail to control constipation in pregnancy, moderate doses of poorly absorbed laxatives may be used. A bulk forming laxative should be tried first. An osmotic laxative can also be used. Senna may be suitable if a stimulant effect is necessary. See BNF or the Summary of Product Characteristics for advice re individual preparations.
### Table Illustrating Formulary Drug Choices

<table>
<thead>
<tr>
<th>Indication</th>
<th>Laxative</th>
<th>Dose</th>
<th>Time to take effect</th>
<th>Additional information</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Acute Constipation</strong></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>1st line oral therapy</td>
<td>Senna tablets</td>
<td>2–4 tablets at night</td>
<td>8–12 hours</td>
<td>Chronic use may lead to colonic atony, tolerance fluid and electrolyte imbalance. Doses may be further increased if required</td>
</tr>
<tr>
<td></td>
<td>Senna liquid 7.5ml/5ml</td>
<td>10–20ml at night</td>
<td></td>
<td></td>
</tr>
<tr>
<td>2nd line oral therapy</td>
<td>Docusate sodium liquid 50mg/ml</td>
<td>300mg daily in divided doses</td>
<td>1–2 days</td>
<td></td>
</tr>
<tr>
<td></td>
<td>Docusate sodium capsules 100mg</td>
<td>(Max 500mg daily)</td>
<td></td>
<td></td>
</tr>
<tr>
<td>3rd line oral therapy</td>
<td>Bisacodyl 5mg tablets</td>
<td>1-2 tablets at night</td>
<td>10-12 hours</td>
<td></td>
</tr>
<tr>
<td></td>
<td>Bisacodyl 10mg suppositories</td>
<td>Insert one in rectum in morning</td>
<td>20-60 minutes</td>
<td></td>
</tr>
<tr>
<td></td>
<td>Sodium Citrate Rectal (Microenema)</td>
<td>Insert one (5ml single dose) as required</td>
<td>5-15 minutes</td>
<td></td>
</tr>
<tr>
<td><strong>Chronic Constipation</strong></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>1st line oral therapy</td>
<td>Macrogols (Laxido/Cosmocol)</td>
<td>1–3 sachets daily in divided doses</td>
<td>1–3 days</td>
<td>Dose can often be reduced to 1–2 sachets daily for maintenance.</td>
</tr>
<tr>
<td>2nd line oral therapy</td>
<td>Docusate sodium liquid</td>
<td>300mg daily in divided doses</td>
<td>1–2 days</td>
<td>Dose can be reduced to 1-2 caps daily (100-200mg daily).</td>
</tr>
<tr>
<td></td>
<td>Docusate sodium capsules</td>
<td>(Up to 5 daily in divided doses for up to 2 weeks).</td>
<td></td>
<td></td>
</tr>
<tr>
<td>3rd line oral therapy</td>
<td>Lactulose</td>
<td>15ml twice daily</td>
<td>2–3 days</td>
<td>Only where other laxatives cannot be tolerated. Unsuitable if rapid relief is required. Maintenance dose can be reduced to meet individual needs. Ensure adequate fluid intake.</td>
</tr>
<tr>
<td></td>
<td>Ispaghula Husk (only for individuals with low fibre intake).</td>
<td>One sachet morning and afternoon</td>
<td>1–2 days</td>
<td>Ensure adequate fluid intake. Avoid in intestinal obstruction, decreased muscle tone and following bowel surgery. Do not give at night.</td>
</tr>
<tr>
<td>Indication</td>
<td>Laxative</td>
<td>Dose</td>
<td>Time to take effect</td>
<td>Additional information</td>
</tr>
<tr>
<td>---------------------------------------------------------------------------</td>
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<td>----------------------------------------------------------------------</td>
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<td>----------------------------------------------------------------------------------------</td>
</tr>
<tr>
<td>Impaction – to use osmotic and stimulant concomitantly</td>
<td>Sodium Citrate Rectal (Micro enema)</td>
<td>Insert one (5ml single dose) as required</td>
<td>5-15 minutes</td>
<td>Reconstituted solution should be kept in refrigerator and discarded after 6 hours</td>
</tr>
<tr>
<td>1st line oral therapy</td>
<td>Macrogols (Cosmocol/Laxido)</td>
<td>4 sachets first day increasing to max of 8 sachets daily. Dissolve 2 sachets in 250ml water Total daily dose taken within 6 hours, for up to 3 days</td>
<td>1-3 days</td>
<td></td>
</tr>
<tr>
<td>Chronic analgesic/opioid induced constipation e.g. codeine, dihydrocodeine, tramadol, morphine</td>
<td>1st line oral therapy</td>
<td>2–4 tablets at night</td>
<td>8-12 hours</td>
<td>Chronic use may lead to colonic atony, tolerance, fluid and electrolyte imbalance. Consider intermittent usage or lowest effective dose.</td>
</tr>
<tr>
<td></td>
<td>Senna tablets</td>
<td>10-20ml at night</td>
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<td></td>
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<tr>
<td></td>
<td>Senna liquid</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>2nd line oral therapy</td>
<td>Docusate sodium liquid 50mg/5ml</td>
<td>Up to 500mg per day in divided doses</td>
<td>1-2 days</td>
<td>For maintenance dose reduce to meet individual needs</td>
</tr>
<tr>
<td></td>
<td>Docusate sodium capsules 100mg</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>3rd line oral therapy</td>
<td>Bisacodyl Tabs or Suppositories 10mg</td>
<td>1-2 tablets at night</td>
<td>10-12 hours</td>
<td></td>
</tr>
<tr>
<td></td>
<td>Insert one in rectum in morning</td>
<td>20-60 minutes</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Naloxegol Tablets 12.5mg and 25mg tablets (Specialist use only)</td>
<td>25mg daily</td>
<td></td>
<td></td>
<td>May colour urine red Only when response to other laxatives is ineffective. Danthron is eliminated both in urine and faeces and can cause painful skin damage (‘danthron burn’). Avoid using if incontinent of faeces and/or urine.</td>
</tr>
<tr>
<td>For use only in care of the terminally ill.</td>
<td>Co-danthrusate capsules 5ml–15ml at night</td>
<td></td>
<td>6–12 hours</td>
<td></td>
</tr>
<tr>
<td>Co-danthrusate suspension</td>
<td>1–3 capsules at night</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Indication</td>
<td>Laxative</td>
<td>Dose</td>
<td>Time to take effect</td>
<td>Additional information</td>
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<td>------------------------------------------------</td>
<td>----------------------------------------------------</td>
<td>----------------------------------------------------------------------</td>
<td>---------------------</td>
<td>---------------------------------------------------------------------------------------</td>
</tr>
<tr>
<td>Laxative resistant chronic constipation in women</td>
<td>Prucalopride 1mg &amp; 2mg tablets (Specialist use only)</td>
<td>2mg daily for adult women under 65 years. 1mg daily for women over 65 years</td>
<td>Few days or not at all</td>
<td>Treatment should be reconsidered if there is a lack of effect after four weeks.</td>
</tr>
<tr>
<td>Constipation in Irritable Bowel Syndrome</td>
<td>1\textsuperscript{st} Line – Ispaghula Husk</td>
<td>One sachet morning and afternoon</td>
<td>2 to 3 days</td>
<td></td>
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<tr>
<td></td>
<td>2\textsuperscript{nd} line or in combination – Macrogol (Cosmocol/Laxido) or Senna tablets (short term use only.)</td>
<td>1–3 sachets daily in divided doses</td>
<td>2 to 3 days</td>
<td>Lactulose is not recommended</td>
</tr>
<tr>
<td>Idiopathic Constipation</td>
<td>Sodium Picosulfate (specialist use only)</td>
<td></td>
<td></td>
<td>Occasional use only. Needs regular monitoring. Usually combined with other laxatives</td>
</tr>
<tr>
<td>Laxative resistant chronic idiopathic constipation</td>
<td>Lubiprostone 24mcg capsules (Specialist use only)</td>
<td>24mcg twice daily</td>
<td></td>
<td>A course of treatment for constipation with Lubiprostone is 2 to 4 weeks. Treatment with lubiprostone should be stopped if there is no response to lubiprostone after at least 2 weeks.</td>
</tr>
</tbody>
</table>
MANAGEMENT OF CONSTIPATION IN ADULTS IN THE COMMUNITY
>18 YEARS AND NON-PREGNANT

Information on Laxatives and Usual Dose

1. Bulk laxatives:
   - Isphagula husk (Fybogel®) - once or twice daily

2. Stimulant laxatives:
   - Senna 2-4 tablets at night
   - Bisacodyl 5-10mg at night
   - Glycerine suppositories prn only

3. Osmotic laxatives:
   - Macrogol 3350 (Cosmocal/Laxido) 1-3 sachets a day
   - Sodium Citrate rectal - microenema

4. Faecal softeners
   - Docusate Sodium up to 300mg daily in divided doses

Doses shown are recommended doses and should be titrated towards maximum tolerated doses.

CONSTITUTION
6 MONTHS HISTORY
- Bowel movement <2/week
- Straining on defaecation
- Incomplete evacuation requiring digital manipulation
- Review bowel habit diary as completed by patient

Review drug history - opioids, calcium channel blockers, iron supplements, diuretics and anti-depressants etc.
- Routine bloods - LFTs, TTGs and serum calcium levels
- Lifestyle advice
- Increase oral fluids
- Increase fibre
- Dietary advice
- See Constipation Guidelines Appendices 1-5

ALARMING FEATURES:
- Rectal/abdominal mass
- Severe abdominal pain
- Unexplained weight loss
- Iron Deficiency Anaemia (low MCV/MCH)
- Rectal bleeding
- Family history of colon cancer
- Narrowing of stool calibre
- Tenesmus

Consultant/specialist initiation only, once therapy is found to be effective prescribing can be transferred to primary care:
- Prucalopride 2mg daily for adult women under 60.
- Prucalopride 1mg daily for women over 60 - As per NICE TA 211 (for women only) after 6 months treatment of at least 2 classes at maximum tolerated doses, review after 4 weeks of treatment.
- other laxative treatment options have been ineffective or contraindicated.
- Naloxegol – 12.5-25mg once daily for treating opioid-induced constipation - As per NICE TA 345 in adults whose constipation has not adequately responded to laxatives.
10. Education & Training

Training will be available for community nursing teams co-ordinated by the Continence Service. The guidelines will be disseminated widely across the health economy and locally training arranged as appropriate.

11. References


3. Bristol Stool Chart, Dr K.W. Heaton and S.J. Lewis, University of Bristol.


5. NICE technology Appraisal guidance 318 (Jul 2014) Lubiprostone for treating chronic idiopathic constipation.

6. NICE technology Appraisal guidance 345 (Jul 2015) Naloxegol for treating opioid-induced constipation.


12. Useful Contacts

Continence Service: 01384 321517

Colorectal Service Russells Hall Hospital: 01384 244286
## RISK ASSESSMENT TOOL

### Questions

If more than 4 ticks full assessment is needed

1. How long have you had the problem?
2. Do you feel the need to go and then can’t
3. Is Defecation painful?
4. Can you pass stools easily or do you have to strain?
5. How often do you go and how would you describe the stools?
6. How is this different from your usual pattern?
7. Do you need to manually assist? E.g., perineal support, vaginal support (thumb in vagina) or manual evacuation.

### Medical condition

- Cancer
- Clinical depression
- Diabetes
- Haemorrhoids, anal fissure rectal problems
- History of constipation
- Impaired cognition
- Multiple Sclerosis
- Parkinson’s
- Rheumatoid arthritis
- Post-operative
- Spinal cord injury
- Stroke
- Coeliac Disease
- Other

### Current medication

- Aluminium antacids
- Anticholinergics
- Anti-Parkinson drugs
- Antipsychotic
- Calcium channel blockers
- Calcium supplements
- Diuretics
- Iron supplements
- NSAIDS
- Opioids
- Tricyclic antidepressants
- Polypharmacy (more than 5 drugs)

### Mobility

- Restricted to bed
- Restricted to wheelchair/chair
- Walks with assistance/aids
- Walks short distance but less than 0.5km

### Toilet facilities

- Needs bed pan/Commode
- Has a commode by bed
- Supervised use of the toilet/commode
- Raised toilet seat/foot stools

### Nutritional intake

- Fibre intake less than 6g per day
- Difficulty swallowing/chewing
- Needs assistance to eat

### Fluid intake

- Minimum per day
- How long have you had constipation

### ACTION CHECKLIST

- Complete full bowel assessment using Locally approved care pathway
- Monitor and record bowel movements daily using the Bristol Stool Chart and bowel record chart
- Stool type 1 or 2 prescribe appropriate laxative therapy
- Advise on toileting position
- Review medication including over the counter medicines
- Advise on ways to improve mobility
- Encourage patients to achieve at least minimum fluid intake
- Improve nutrition according to nutritional score

The following questions can help to identify and assess the severity of constipation:

1. How long have you had the problem?
2. Do you feel the need to go and then can’t
3. Is Defecation painful?
4. Can you pass stools easily or do you have to strain?
5. How often do you go and how would you describe the stools?
6. How is this different from your usual pattern?
7. Do you need to manually assist? E.g., perineal support, vaginal support (thumb in vagina) or manual evacuation.

Signature………………………………………
Date…………………………………………
Base…………………………………………
Here are some ideas to help you increase your daily fibre intake

<table>
<thead>
<tr>
<th>Food</th>
<th>Fibre (g)</th>
</tr>
</thead>
<tbody>
<tr>
<td>A bowl of Shreddies</td>
<td>6.0g</td>
</tr>
<tr>
<td>A wholemeal cob</td>
<td>4.8g</td>
</tr>
<tr>
<td>An apple</td>
<td>1.7g</td>
</tr>
<tr>
<td>A portion of brown rice</td>
<td>2.5g</td>
</tr>
<tr>
<td>2 tomatoes</td>
<td>1.7g</td>
</tr>
<tr>
<td>A wholemeal fruit scone</td>
<td>2.6g</td>
</tr>
<tr>
<td><strong>TOTAL: 19.3g</strong></td>
<td></td>
</tr>
<tr>
<td>A portion of baked beans</td>
<td>13.2g</td>
</tr>
<tr>
<td>2 slices of wholemeal bread</td>
<td>5.2g</td>
</tr>
<tr>
<td><strong>TOTAL: 18.4g</strong></td>
<td></td>
</tr>
<tr>
<td>A jacket potato</td>
<td>3.2g</td>
</tr>
<tr>
<td>4 figs</td>
<td>10g</td>
</tr>
<tr>
<td>A bowl of fruit and fibre</td>
<td>5.1g</td>
</tr>
<tr>
<td><strong>TOTAL: 18.3g</strong></td>
<td></td>
</tr>
<tr>
<td>8 prunes</td>
<td>4.8g</td>
</tr>
<tr>
<td>A portion of whole-wheat pasta</td>
<td>6.0g</td>
</tr>
<tr>
<td>Mixed salad</td>
<td>2.7g</td>
</tr>
<tr>
<td>A bowl of porridge</td>
<td>4g</td>
</tr>
<tr>
<td>A banana</td>
<td>2.4g</td>
</tr>
<tr>
<td>A pear</td>
<td>2.3g</td>
</tr>
<tr>
<td><strong>TOTAL: 19.9g</strong></td>
<td></td>
</tr>
</tbody>
</table>
FLUID INTAKE MATRIX
TO DETERMINE SUGGESTED
VOLUME INTAKE PER 24 HOURS

This matrix form is used following an assessment for continence; it is a guide to assist patients reach their optimum fluid intake whilst following a treatment plan.

It is suggested that patients fall within a margin of error of +/-10% - the guideline applies to body frame and gross obesity should not be taken as a guide for increasing fluid. Activity levels should be taken into account.

<table>
<thead>
<tr>
<th>PATIENT'S WEIGHT Stones</th>
<th>KGs</th>
<th>ML</th>
<th>FLUID OZ'S</th>
<th>PINT'S</th>
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</thead>
<tbody>
<tr>
<td>6</td>
<td>38</td>
<td>1,190</td>
<td>42</td>
<td>2.1</td>
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<tr>
<td>7</td>
<td>45</td>
<td>1,275</td>
<td>49</td>
<td>2.5</td>
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<tr>
<td>8</td>
<td>51</td>
<td>1,446</td>
<td>56</td>
<td>2.75</td>
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<tr>
<td>9</td>
<td>57</td>
<td>1,786</td>
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<td>10</td>
<td>64</td>
<td>1,981</td>
<td>70</td>
<td>3.5</td>
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<tr>
<td>11</td>
<td>70</td>
<td>2,179</td>
<td>77</td>
<td>3.75</td>
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<tr>
<td>12</td>
<td>76</td>
<td>2,377</td>
<td>84</td>
<td>4.2</td>
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<td>13</td>
<td>83</td>
<td>2,575</td>
<td>91</td>
<td>4.5</td>
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<td>89</td>
<td>2,773</td>
<td>98</td>
<td>4.9</td>
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<td>15</td>
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<td>2,971</td>
<td>105</td>
<td>5.25</td>
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<td>16</td>
<td>102</td>
<td>3,136</td>
<td>112</td>
<td>5.5</td>
</tr>
</tbody>
</table>

REFERENCE:
# Managing Constipation - Bowel Habit Diary

<table>
<thead>
<tr>
<th>Date</th>
<th>Time</th>
<th>Stool type (see descriptions)</th>
<th>Did you reach the toilet on time?</th>
<th>Did you use a lot of toilet paper?</th>
<th>Did you mark your underwear or pad?</th>
<th>Did you strain?</th>
<th>Any other comments e.g. blood/mucus</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
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<td>Yes/No</td>
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</tbody>
</table>

**Client/Patient’s Carer/Advocate to complete:-**
## Bowel Habit Diary (Carer/Advocate to complete)

<table>
<thead>
<tr>
<th>Date</th>
<th>Time</th>
<th>Stool type (see descriptions)</th>
<th>Reached the toilet on time?</th>
<th>Used a lot of toilet paper?</th>
<th>Marked underwear or pad?</th>
<th>Any straining?</th>
<th>Any other comments e.g. blood/mucus</th>
<th>Carers/Advocates Initials</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
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<td>Yes/No</td>
<td>Yes/No</td>
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**SIGNATURE WHEN COMPLETED:**
To be used as part of agreed treatment plan.
Consent re monitoring of bodily functions to be discussed with client/patient/carer and appropriate managers.
## FOOD & FLUID RECORD DIARY

<table>
<thead>
<tr>
<th>Name:</th>
<th>Date:</th>
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<td>WEDNESDAY</td>
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<td>THURSDAY</td>
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<td>SATURDAY</td>
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<td>SUNDAY</td>
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Management of Constipation in Palliative Care

Opioid Induced constipation

This management guidance is taken from the UK Palliative Care Formulary (PCF) Guidelines: Opioid – Induced constipation. The formulary choices outlined here are compatible with those in the main document.

Although some strong opioids are less constipating than morphine (e.g. buprenorphine, fentanyl, methadone, tramadol), most patients receiving any opioid regularly will need a laxative concurrently. Thus, as a general rule, all patients prescribed morphine (or other opioid) should also be prescribed a laxative. The aim is to achieve a regular bowel action without straining, generally every 1–3 days.

Ask about the patient's past (premorbid) and present bowel habit and use of laxatives; record the date of last bowel action. Palpate for faecal masses in the line of the colon; examine the rectum digitally if the bowels have not been open for >3 days or if the patient reports rectal discomfort or has diarrhoea suggestive of faecal impaction with overflow.

For inpatients, keep a daily record of bowel actions. Encourage fluids generally, and fruit juice and fruit specifically.

Please refer to UK Palliative Care Formulary 5th Edition (PCF5) (www.palliativedrugs.com) and West Midlands Palliative Care Guidelines for more information.
What is Normal Bowel Function?

Heaton and Lewis, University of Bristol

People’s perceptions of constipation vary greatly and normal bowel function may involve defecation three times daily or once every three days, but diagnosis may take place when there is a marked reduction in the amount of stools and/or reduced frequency of defecation.
Appendix 8
Management of Adult Constipation by Nurses trained in Digital Rectal Examination

Alarm Signs:
- Rectal Bleeding
- Passing Mucous PR
- Weight Loss
- Anorexia
- Tenesmus (painful and ineffectual straining)

Patient presenting with suspected constipation?

YES → Advise on ‘normal’ bowel function

NO → Abnormal bowel function / altered routine?

YES → Underlying cause?

e.g. Neurological disorder, bowel disease, drug treatment

NO → Functional Constipation

Discuss with GP, Treat underlying cause. Consider referral to colorectal service if appropriate

PATIENT DISTRESSED?

YES → Dietary and lifestyle advice
Give information leaflet

NO → Keep Bowel Diary

Fluid intake to 2 litres  Exercise  Mobility  Dietary Fibre
Re-educate e.g. gastro-colic reflex

EFFECTIVE → Review within 2 days
(Leave Contact Number)

INEFFECTIVE → Review within 1-3 days
Document fully in patient notes

Refer to GP/ Continence Service/ GI department

DIGITAL RECTAL EXAMINATION (Only carried out by appropriate trained nurses)

Acute Constipation

For hard impacted stools use stimulant

EFFECTIVE → Continue advice to prevent recurrence

Chronic Constipation

Regular bulk forming agent or osmotic

Faecal Impaction

Micro-enema followed by maintenance treatment e.g. regular bulk forming agent or osmotic and regular review

INEFFECTIVE or complicated management

Constipation due to chronic opiate use

Osmotic/Stimulant

add stool softener

Review within 1-3 days
Document fully in patient notes

Refer to GP/ Continence Service/ GI department

EFFECTIVE → Continue advice to prevent recurrence
Prucalopride
For the treatment of chronic constipation in women – NICE TA211

This document supports the use and transfer of an agent that has been approved for initiation and maintenance of prescribing by Specialists and transfer to Primary Care prescribing when appropriate.

The specialist is to complete and send to the GP to continue treatment.

<table>
<thead>
<tr>
<th>Inclusion Criteria:</th>
<th>Chronic constipation in women only which has failed to respond to treatment with at least two laxatives from different classes at the highest tolerated recommended doses for at least six months.</th>
</tr>
</thead>
<tbody>
<tr>
<td>List TWO laxatives from two different classes already tried:</td>
<td>Is this the highest tolerated dose</td>
</tr>
<tr>
<td>Name</td>
<td>Dose</td>
</tr>
<tr>
<td>Invasive treatment for constipation is being considered?</td>
<td>Y/N</td>
</tr>
<tr>
<td>Treatment with prucalopride has been assessed by the specialist after 4 weeks</td>
<td>Y/N</td>
</tr>
<tr>
<td>Date of initiation of treatment:</td>
<td></td>
</tr>
<tr>
<td>Date of 4 week reassessment of treatment:</td>
<td></td>
</tr>
<tr>
<td>If ineffective or not tolerated after 4 weeks, the woman should be re-examined and the benefit of continuing treatment reconsidered. Treatment continues to be effective and is tolerated:</td>
<td>Y/N</td>
</tr>
</tbody>
</table>

Guidance on dosing and continuation of therapy by GP:

<table>
<thead>
<tr>
<th>Dosing Information:</th>
<th>Women: 2 mg prucalopride once daily. (Doses over 2 mg daily are not expected to increase efficacy) Elderly women (&gt;65 years): 1 mg once daily initially; increased to 2 mg once daily if needed. In severe renal impairment (GFR &lt; 30 ml/min/1.73 m2) 1 mg once daily. In severe hepatic impairment (Child-Pugh class C) 1 mg once daily</th>
</tr>
</thead>
<tbody>
<tr>
<td>On-going monitoring</td>
<td>No specific/ mandatory monitoring required. Monitor for adverse drugs reactions as listed in the summary of product characteristics.</td>
</tr>
<tr>
<td>Continuation criteria</td>
<td>If treatment continues to be effective and tolerated by the patient.</td>
</tr>
<tr>
<td>Discontinuation criteria</td>
<td>If treatment ceases to be effective or intolerated.</td>
</tr>
</tbody>
</table>

Specialist details

<table>
<thead>
<tr>
<th>Specialist’s name</th>
</tr>
</thead>
<tbody>
<tr>
<td>Declaration</td>
</tr>
<tr>
<td>Specialist’s signature</td>
</tr>
<tr>
<td>Date</td>
</tr>
<tr>
<td>Contact Details</td>
</tr>
</tbody>
</table>
Appendix 10

Naloxegol

For the treatment of opioid-induced constipation (OIC) in adults – NICE TA345

This document supports the use and transfer of an agent that has been approved for initiation and maintenance of prescribing by Specialists and transfer to Primary Care prescribing when appropriate.

The specialist is to complete and send to the GP to continue treatment.

<table>
<thead>
<tr>
<th>Inclusion Criteria</th>
<th>Naloxegol is a possible treatment for people with opioid induced constipation that has had an inadequate response to laxatives as per NICE TA 345.</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>An inadequate response is defined as opioid induced constipation symptoms of at least moderate severity in at least 1 of the 4 stool symptom domains (that is, incomplete bowel movement, hard stools, straining or false alarms) while taking at least 1 laxative class for at least 4 days during the prior 2 weeks.</td>
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<td></td>
<td>When naloxegol therapy is initiated, it is recommended that all currently used maintenance laxative therapy should be halted, until clinical effect of naloxegol is determined.</td>
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</tbody>
</table>

| Treatment with Naloxegol has been assessed by the specialist Y/N. Date of initiation of treatment: Date of reassessment of treatment: | If ineffective or not tolerated, the patient should be reviewed and the benefit of continuing treatment reconsidered. Treatment continues to be effective and is tolerated: Y/N |
|--------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|

<table>
<thead>
<tr>
<th>Guidance on dosing and continuation of therapy by GP:</th>
<th>Dosing Information: The recommended dose of naloxegol is 25 mg once daily. Naloxegol should be taken on an empty stomach at least 30 minutes prior to the first meal of the day or 2 hours after the first meal of the day. The starting dose for patients with moderate or severe renal insufficiency and those taking moderate CYP3A4 inhibitors (e.g. diltiazem, verapamil) is 12.5 mg.</th>
</tr>
</thead>
<tbody>
<tr>
<td>On-going monitoring</td>
<td>No on-going monitoring required.</td>
</tr>
<tr>
<td>Continuation criteria</td>
<td>If treatment continues to be effective and tolerated by the patient.</td>
</tr>
<tr>
<td>Discontinuation criteria</td>
<td>• If treatment ceases to be effective or not tolerated. See SPC for side effects. • Suspected gastrointestinal obstruction, increased risk of recurrent obstruction • Patients with underlying cancer who are at heightened risk of GI perforation, such as those with: • underlying malignancies of gastrointestinal tract or peritoneum • recurrent or advanced ovarian cancer • vascular endothelial growth factor (VEGF) inhibitor treatment. • Concomitant use with strong CYP3A4 inhibitors (e.g. clarithromycin, ketoconazole, itraconazole or telithromycin; protease inhibitors such as ritonavir, indinavir or saquinavir; grapefruit juice when consumed in large quantities). • Caution should be taken in patients with increased</td>
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33
potential of gastrointestinal perforation and clinically important disruptions of the blood-brain barrier i.e. brain metastases, Alzheimer’s disease. Seek further advice from specialist.

<table>
<thead>
<tr>
<th>Specialist details</th>
<th>Specialist’s name</th>
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</thead>
<tbody>
<tr>
<td>Declaration</td>
<td>I confirm that this patient is eligible to receive Naloxegol under the restrictions listed above.</td>
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<tr>
<td>Specialist’s signature</td>
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<tr>
<td>Date</td>
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<tr>
<td>Contact Details</td>
<td>Telephone: E-mail:</td>
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