

## BNSSG Shared Care Guidance

Please complete all sections

### Section 1: Heading

<b>Drug</b>	Colesevelam
<b>Amber</b> <i>one month</i>	
<b>Indication</b>	Treatment of bile acid malabsorption (in adults) where colestyramine is ineffective or not tolerated.  The safety and efficacy of Colesevelam in children aged 0 to 17 years have not yet been established.

### Section 2: Treatment Schedule

<b>Usual dose and frequency of administration</b> <i>(Please indicate if this is licensed or unlicensed and any relevant dosing information)</i>	2 to 6 tablets daily in two divided doses taken orally with a meal and liquid. Often dose is titrated up according to response. If interaction with other medication is an issue (see below) colesevelam can be taken once a day.  Note this is an off-label indication
<b>Route and formulation</b>	Oral; 625mg tablets
<b>Duration of treatment</b>	Treatment should be stopped after 1 month if patient does not respond. If patient responds well to treatment it can be continued on an ongoing basis.

### Section 3: Monitoring

Please give details of any tests that are required before or during treatment, including frequency, responsibilities (please state whether they will be undertaken in primary or secondary care), cause for adjustment and when it is required to refer back to the specialist.

<b>Baseline tests - where appropriate</b>			
Serum triglyceride levels – safety and efficacy of colesevelam in patients with serum triglyceride levels >3.4mmol/L has not been established and it should be used with caution in these patients.			
<b>Subsequent tests - where appropriate</b> <i>(Please indicate who takes responsibility for taking bloods and interpreting results)</i>			
<b>Test</b>	<b>Frequency</b>	<b>Who by</b>	<b>Action/management</b>
Fasting lipids (especially triglycerides)	Check after 1 year	GP	Refer to specialist if triglycerides >3.4 mmol/L. If triglycerides below 3.4mmol/L no further monitoring required

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## Section 4: Side Effects

Please list only the most pertinent side effects and management. Please provide guidance on when the GP should refer back to the specialist. For everything else, please see BNF or SPC.

Side effects and management	Side effect	Frequency	Action/management
	Flatulence, constipation	Very common	See 'referral back to specialist' box below
	Headache, vomiting, diarrhoea, dyspepsia, abdominal pain, nausea, abdominal distension, abnormal stools, increased serum triglycerides	Common	See 'referral back to specialist' box below
	Dysphagia, myalgia, increased serum transaminases	Uncommon	See 'referral back to specialist' box below
	Pancreatitis	Very rare	See 'referral back to specialist' box below
	Intestinal Obstruction	Not known	Incidence likely to be increased in patients with a history of bowel obstruction or removal and colessevelam is contraindicated in these patients (see section 6)
Referral back to specialist	Serious adverse effects warranting withdrawal of therapy. Intolerance of less serious side effects resulting in patient wishing to stop therapy. Serum triglycerides >3.4mmol/.		

## Section 5: Other Issues

### (e.g. Drug Interactions, Contra-indications, Cautions, Special Recommendations)

Please list only the most pertinent action for GP to take (For full list please see BNF or SPC)

Issues	<p><b>Special Recommendations</b>            Fat soluble deficiency (vitamin A, D,E, K) and folic acid deficiency may be seen with prolonged use. If a patient presents with signs of a deficiency of any of these then their level should be checked and replaced accordingly/referred back to the specialist.</p> <p><b>Drug interactions</b></p> <p>Colesevelam can reduce the absorption of concomitant medication. Patients should be reminded to take colessevelam at least 4 hours before or after any concomitant medication to reduce this risk. Colesevelam can be taken once a day to aid administration.</p> <p>Specific interactions:            Ciclosporin – colessevelam reduces bioavailability of ciclosporin- monitor levels            Anticoagulants – monitor warfarin levels (colessevelam reduces vitamin K absorption)            Oral contraceptives (administer colessevelam at least 4 hours after to minimise interaction risk)            Metformin (modified-release preparations) – monitor for clinical response due to increased metformin exposure            Phenytoin (rare reports of reduced phenytoin levels when administered with colessevelam)</p>
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	<p><b>Contraindications/cautions/special recommendations</b></p> <ol style="list-style-type: none"> <li>1. Hypersensitivity to colessevelam or any of the excipients (contraindication)</li> <li>2. History of bowel or biliary obstruction (contraindication)</li> <li>3. Serum triglyceride level &gt;3.4mmol/L</li> <li>4. The safety and efficacy of colessevelam in patients with dysphagia, swallowing disorders, severe gastrointestinal motility disorders, inflammatory bowel disease, liver failure or major gastrointestinal tract surgery have not been established. Consequently, caution should be exercised when colessevelam is used in patients with these disorders.</li> <li>5. Risk of constipation should be especially considered in patients with coronary artery disease or angina pectoris</li> <li>6. Caution when treating patients with a susceptibility to vitamin K or fat-soluble vitamin deficiencies, such as patients with malabsorption</li> <li>7. Caution with use in pregnancy and breast feeding as the safety has not been established and may cause fat-soluble vitamin deficiency on prolonged use.</li> </ol>
<p><b>Reminder to ask patient about specific problems</b></p>	<p>Not applicable</p>

## Section 6: Advice to the patient

Advice for prescribing clinician to inform patient

1. Patients should be reminded to take colessevelam at least 4 hours before or after any concomitant medication to reduce the risk of that medication not being absorbed
2. Advise patients about possible side effects
3. Advise patients about need for monitoring blood tests

## Section 7: Generic principles of shared care for SECONDARY CARE

*Please do not amend.*

### Core responsibilities

1. Initiating treatment and prescribing for the length of time specified in **section 1**.
2. Undertaking the clinical assessment and monitoring for the length of time specified in **section 1** and thereafter undertaking any ongoing monitoring as detailed in **section 3**.
3. Communicate details of the above in 1 and 2 to GP within the first month of treatment. This information should be transferred in a timely manner.
4. Refer patients to GP and provide information of further action where appropriate e.g. if blood test is due.
5. To provide advice to primary care when appropriate.
6. Review concurrent medications for potential interaction prior to initiation of drug specified in **section 1**.
7. Stopping treatment where appropriate or providing advice on when to stop.
8. Reporting adverse events to the MHRA.
9. Reminder to ask patients about particular problems see **section 5**.

## Section 8: Generic principles of shared care for PRIMARY CARE

*Please do not amend.*

### Core responsibilities

1. Responsible for taking over prescribing after the length of time specified in **section 1**.
2. Responsible for any clinical assessment and monitoring if detailed in **section 3** after the length of time specified in **section 1**.
3. Review of any new concurrent medications for potential interactions.
4. Reporting adverse events to the MHRA.
5. Refer for advice to specialist where appropriate.

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6. Reminder to ask patients about particular problems see **section 5**.

## Section 9: Contact Details

Name	Organisation	Telephone Number	E mail address
Gastroenterology consultants	North Bristol NHS Trust	0117 4146349	<a href="mailto:GastroenterologyandHepatologySecretaries@nbt.nhs.uk">GastroenterologyandHepatologySecretaries@nbt.nhs.uk</a>
Cara Leung and Rebecca Chalker (Specialist Pharmacists)	North Bristol NHS Trust	0117 4142255	<a href="mailto:gastropharmacists@nbt.nhs.uk">gastropharmacists@nbt.nhs.uk</a>
Secretary to Dr Parker and Dr Bell	Weston Area Health Trust	01934 636363 (switch) ext. 3814	Sheena.jeffrey@nhs.net
Hepatology consultants	University Hospital Bristol	0117 3422632 / 3422525/ 3424001	<a href="mailto:GastroHepatologySecretariesBRI@UHBristol.nhs.uk">GastroHepatologySecretariesBRI@UHBristol.nhs.uk</a>

## Section 10: Document Details

Date prepared	Updated March 2022
Prepared by	Cara Leung and Rebecca Chalker (Specialist Pharmacists - Gastroenterology)
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## Section 11: Collaboration

All shared care protocols should be BNSSG wide where possible. Specialists in any one discipline are encouraged to collaborate across the health community in preparing shared care guidance. Please give details

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## Section 12: References

Please list references

1. Dr Reddy's Laboratories, 2021. Colesevelam hydrochloride 625mg film-coated tablets. Available at: <https://www.medicines.org.uk/emc/product/12914/smpc> [Accessed: 01/03/22]
2. National Institute for Health and Care Excellence (NICE), 2013. Bile Acid Malabsorption: Colesevelam. Evidence Summary [ESU] M22]. Available at: <https://www.nice.org.uk/advice/esuom22/> [Accessed: 11/6/20]
3. BNF, 2022 [online]. Available from: <https://bnf.nice.org.uk/drug/colesevelam> [Accessed: 01/03/22].

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