RELEVANT ACUTE TRUST LOGO

WORKING IN PARTNERSHIP WITH

Surrey (East Surrey CCG, Guildford & Waverley CCG, North West Surrey CCG, Surrey Downs CCG & Surrey Heath) Crawley CCG and Horsham & Mid-Sussex CCG

SHARED CARE Guideline – Amber Traffic Light Classification		
Name of medicine	Ranolazine (Ranexa ®)	
Indication (including whether for adults and/or children)	As adjunctive therapy in the treatment of stable angina pectoris in patients inadequately controlled or intolerant of first-line antianginal therapies	
PCN policy statement reference (if applicable)	PCN 13-2012	
Author(s): Clare Curran **Organisation(s):** Guildford & Waverley CCG		
Version: 3.0	**PCN recommendation date:** February 2017	**Review date:** February 2019

The Shared Care Guideline (SCG) is intended to facilitate the accessibility and safe prescribing of complex treatments across the secondary/primary care interface.
This **AMBER** shared care sets out the patient pathway relating to this medicine and any information not available in the British National Formulary and manufacturer's Summary of Product Characteristics. Prescribing must be carried out with reference to those publications.
The SCG must be used in conjunction with the PCN agreed core roles and responsibilities stated in annex A.
An agreement notification form is included in annex B for communication of request for shared care from provider and agreement to taken on prescribing by primary care.

Roles and Responsibilities

Listed below are specific medicine/indication related responsibilities that are additional to those core roles and responsibilities that apply to all SCGs listed in annex A.

Consultant / Specialist

- Initiate treatment with ranolazine in those patients whose angina is inadequately controlled despite maximally tolerated medical treatment and in whom the up-titration or addition of other standard antianginal agents is contraindicated or not tolerated, due to their effect on heart rate and/or blood pressure, and are ineligible for revascularisation. The recommended initial dose of ranolazine is 375mg twice daily.
- Give the patient the ranolazine package leaflet and the Patient Alert Card and instruct to present their Patient Alert Card and medication list to their health care professional at each visit.
- Assess symptom relief 2 to 4 weeks after treatment initiation.
- Up-titrate dose from 375mg twice daily to 500mg twice daily if angina persists. The dose may be further adjusted according to response up to a recommended maximum of 750mg twice daily but reduced if not tolerated to 375mg - 500mg twice daily.
- Whilst the patient is being up-titrated the consultant is responsible for prescribing.
- Discharge patient back to GP once patient is stable on maximum tolerated dose. Communicate to Primary Care Prescriber regarding outcome of cardiac investigation and treatment to date.

Primary Care Prescriber

- Ensure the patient has received the ranolazine package leaflet and the Patient Alert Card and remind them to present their Patient Alert Card and medication list to their health care professional at each visit.
- If side effects are experienced (see SPC) e.g.: dizziness, nausea, vomiting, discuss with initiating clinician (if required) with regards down-titrating dose. Discontinue treatment if side effects do not resolve after dose reduction.
- Stop medication if patient is not experiencing relief of angina symptoms despite taking maximum tolerated dose. Notify specialist of treatment failures.
- Assess the patient after six months and review the patient at least annually
- Check renal function at every 6 months during treatment with ranolazine.

Patient, Relatives, Carers

- Read the patient information leaflet and Patient Alert Card included with your medication and report any side effects or concerns you have to the specialist or GP. Present the Patient Alert Card to your healthcare professional at each visit.
- Report deterioration in symptoms to the GP.
- Seek immediate medical advice if experiencing a prolonged episode of angina.

Key information on the medicine

Please refer to the current edition of the British National Formulary (BNF), available at www.bnf.org, and Summary of Product Characteristics (SPC), available at www.medicines.org.uk for detailed product and prescribing information and specific guidance.

Background to disease and use of medicine for the given indication
Ranolazine (Ranexa®) is an antianginal drug that works without clinically significant effects on heart rate or blood pressure. It has a novel mechanism of action, involving selective inhibition of the late sodium current. Ranolazine is licensed for use as an add-on therapy for the symptomatic treatment of patients with stable angina pectoris who are inadequately controlled or intolerant to first-line therapies (such as betablockers and/or calcium antagonists).

Indication
The Prescribing Clinical Network (PCN) recommends the use of ranolazine in patients who have persistent angina symptoms, despite maximally tolerated medical treatment and in whom the up-titration or addition of other agents is contraindicated or not tolerated, due to their effect on heart rate and/or blood pressure, and who are ineligible for revascularisation. Ranolazine is considered AMBER on the Traffic Light System.

Dosage and Administration
Refer to current Summary of Product Characteristics (SPC): www.medicines.org.uk

Monitoring

Test	Frequency	Abnormal Result	Action if Abnormal Result
Renal function	6 months	creatinine clearance < 30 ml/min creatinine clearance 30–80 ml/min	Contraindicated in severe renal impairment Caution in mild to moderate renal impairment

Cautions, contraindications
Refer to current Summary of Product Characteristics (SPC): www.medicines.org.uk

Adverse effects
Refer to current Summary of Product Characteristics (SPC): www.medicines.org.uk

Drug interactions
Refer to current Summary of Product Characteristics (SPC): www.medicines.org.uk

Support and Advice for the Primary Care

Name	Speciality	Telephone No.	Email address
XXXXX	XXXXX	XXXXX	XXXXX
Hospital Pharmacy	XXXXX	XXXXX	XXXXX
Out of Hours	XXXXX	XXXXX	XXXXX

Annex A: PCN agreed core roles and responsibilities for the shared care of medicines

Patients

To get the most out of your treatment it's important that you work together with your specialist. You must follow these guidelines to ensure your own safety, health and wellbeing.

- You must make sure that you understand about your treatment
- If you do not understand ask for more information from the person prescribing the medicine
- Read the Patient Information Leaflet included with your medication. It will provide you with information about your medication
- You must raise concerns about your treatment with the person prescribing the medicine
- Talk to the specialist and come to an agreement of how the treatment should be provided to you
- Give permission to have aspects of your care communicated to healthcare providers
- You must attend all appointments
- You must keep a written list of all of the medicines you are taking
- You must keep lists of any additional vitamins, minerals, or other dietary supplements
- You must bring these lists with you each time you visit a healthcare provider or are admitted to a hospital
- You must carry these lists on you in case of an emergency
- You must not let anyone else take your medication.

It is your responsibility to follow these guidelines. The guidelines are here for your safety, health and wellbeing.

If you would like more information on your rights, roles and responsibilities in your healthcare please ask a NHS professional for information on the NHS constitution or visit, www.gov.uk/government/publications/the-nhs-constitution-for-england

Relatives and Carers

- To support the patient in fulfilling their roles and responsibilities as outlined above.

Consultant/ Specialist

- Be aware that if you recommend that a colleague, for example a junior doctor or GP, prescribes a particular medicine for a patient, you must consider their competence to do so. You must satisfy yourself that they have sufficient knowledge of the patient and the medicine, experience (especially in the case of junior doctors) and information to prescribe. You should be willing to answer their questions and otherwise assist them in caring for the patient, as required(Ref GMC).
- Be aware that if you delegate assessment of a patients' suitability for a medicine, you must be satisfied that the person to whom you delegate has the qualifications, experience, knowledge and skills to make the assessment. You must give them enough information about the patient to carry out the assessment required.
- Be aware that you are asking the GP to take full medicolegal responsibility for the prescription they sign(Ref GMC). For this reason the shared care guidelines (SCGs) are agreed at the PCN with input from specialists and GPs, and, for individual patients, the patient's GP must agree to take over responsibility before transfer of care, before the patient is discharged from specialist care.
- Be aware of the formulary status and the traffic light classification of the medicine you are prescribing within the patient's CCG
- Assume clinical responsibility for the guidance given in the SCG, and where there is new information needed on the SCG to liaise with your Formulary Pharmacist who will facilitate an update via the PCN

- Evaluate the suitability of the patient for treatment, including consideration of the patient's current medication and any significant interactions.
- Discuss and provide the patient with information about the reason for choosing the medicine, the likelihood of both harm and benefits, consequences of treatment, and check that their treatment choice is consistent with their values and preferences
- Advise patient of unlicensed status of treatment (including off-label use) if appropriate and what this may mean for their treatment.
- Undertake baseline monitoring and assessment.
- Prescribe initial treatment and provide any associated training and counselling required.
- Continue to prescribe and supply treatment with appropriate monitoring until the patient's condition is stable; the patient is demonstrably benefiting from the treatment and is free from any significant side effects.
- Liaise with the primary care prescriber to agree to share the patient's care and provide relevant accurate, timely information and advice.
- Follow up and monitor the patient at appropriate intervals. If the primary care prescriber feels unable to accept clinical responsibility for prescribing then the consultant must continue to prescribe the treatment to ensure consistency and continuity of care. Provide clear and effective communication with patient, relatives and carers, and use of communication support if necessary.
- Only advise the patient that shared care will take place, and prescribing will be transferred, once the primary care prescriber has agreed to share responsibility of the patient care, and that this has been confirmed in writing.
- Ensure that the patient (and carer/relatives) are aware of their roles and responsibilities under the SCG
- Provide sufficient information and training for the patient to participate in the SCG

Primary Care Prescriber

- Be aware of the formulary and traffic light status of the medicine you have been asked to prescribe.
- Be aware that Amber medicines have been assessed by the PCN as requiring careful transition between care settings but SCGs will be available to support safe transfer of care.
- It would be usual for GPs to take on prescribing under a formal SCG. If you are uncertain about your competence to take responsibility for the patient's continuing care, you should seek further information or advice from the clinician with whom the patient's care is shared or from another experienced colleague. If you are still not satisfied, you should explain this to the other clinician and to the patient, and make appropriate arrangements for their continuing care.
- Be aware that if you prescribe at the recommendation of another doctor, nurse or other healthcare professional, you must satisfy yourself that the prescription is needed, appropriate for the patient and within the limits of your competence (Ref GMC).
- Be aware that if you prescribe, you will be responsible for any prescription you sign (Ref GMC).
- Keep yourself informed about the medicines that are prescribed for the patient
- Be able to recognise serious and/ or frequently occurring adverse side effects, and what action should be taken if they occur.
- Make sure appropriate clinical monitoring arrangements are in place and that the patient and healthcare professionals involved understand them
- Keep up to date with relevant guidance on the use of the medicines and on the management of the patient's condition.
- Respond to requests to share care of patients in a timely manner, in writing (including use of form in annex B)
- Liaise with the consultant to agree to share the patient's care in line with the SCG in a timely manner.

All

- Where it has been identified that a SCG requires update e.g. new information needed, liaise with the SCG author and/or your organisation PCN representative who will facilitate an update via the PCN.

Annex B: Shared care agreement notification form for medicines and indications approved as amber on the Surrey PAD or Crawley, Horsham and Mid-Sussex net formulary.

For the attention of the Practice Manager

FAX – Confirm you have the correct Safe Haven Fax Number before sending
E-mail – Confirm both sender and recipient e-mail addresses are nhs.net before sending

To:	[Recipient Name]	Fax:	[fax number]
From:	[Your Name]	Date:	[Click to select date]
Re:	[Subject]	Pages:	[number of pages]
cc:	[Name]		

[Notes]

Name of medicine	Ranolazine
Indication	As adjunctive therapy in the treatment of stable angina pectoris in patients inadequately controlled or intolerant of first-line antianginal therapies

Person removing form from fax machine	
Relevant patients GP available to action within 5 days (if not Trust needs to be informed on day of receipt of request)	Yes/ No
If GP is NOT available within 5 days, please communicate to the requesting specialist the date when the GP will be available	

Hospital/ Patient information		**Practice information**	
Consultant Making Request		GP Name:	
Consultant Speciality Details:		Practice:	
Patient Name:		I agree to undertake shared care:	
Patient NHS Number:		I do not agree to undertake shared care:	
Patient Hospital Number:		If NOT please give reasons:	
Patient DOB:		Signed:	
Drug Name/ Dose:		Date:	
Next Prescription Due:		Please return form to:	Specialist safe haven fax number
Discharge letter written and sent:			
Please refer to the Surrey PAD or Crawley, Horsham and Mid-Sussex net formulary for relevant shared care documents			

Primary Care Prescriber should reply within 5 days of receipt of this form indicating participation (or not) in shared care of the patient