The Peripheral Arterial Disease GDG comments on the NICE TA ,'Peripheral arterial disease - cilostazol, naftidrofyryl oxalate, pentoxifylline and inositol nicotinate: appraisal consultation document'		
	GDG Comment	Relevant section of the ACD
Has all of the relevant evidence been taken into account?	We are satisfied that all the relevant evidence has been taken into account.	
Are the summaries of clinical and cost effectiveness reasonable interpretations of the evidence?	The GDG would like to comment on the use of maximum walking distance (MWD) as the main outcome indicator and the use of MWD as an accurate measure to calculate quality of life (QoL) in patients with intermittent claudication. We acknowledge the lack of outcome data directly measuring QoL in the randomised trials and the choice of MWD as the main indicator of outcomes because of the limited availability of better outcome data. However we are concerned that the ACD does not reflect the limitations in using MWD or the uncertainty in the use of MWD to calculate QoL. We are keen to see these limitations reflected in the TA and a research recommendation that future studies should include outcome measures that more accurately reflect patient quality of life and functional ability.	**Section 4** **4.3.6** The Committee considered the evidence for the clinical effectiveness of cilostazol, naftidrofuryl oxalate, pentoxifylline and inositol nicotinate presented by the Assessment Group. The Committee noted that the trials reported a number of endpoints measuring efficacy including maximum walking distance, pain-free walking distance and the ankle brachial pressure index. ..... The Committee agreed that it was appropriate to focus on the Assessment Group's analyses of maximum walking distance **4.3.14** The Committee recognised the limited published evidence for quality of life associated with these drugs, and agreed that the approach used by the Assessment Group to obtain utility values for the economic model was acceptable.
	We are concerned this section may imply that angioplasty is first line treatment for this group of patients. This is not the case, though there are patients where the use of vasoactive drugs to try and delay angioplasty does not appear to have a valid rationale and angioplasty maybe an appropriate initial therapy.	**4.3.3** The clinical specialists said that most clinicians offer vasodilator therapy only to those patients for whom angioplasty is considered an inappropriate treatment or in whom

	We would be keen to see this clarified in the document.	angioplasty has failed, although some offer vasodilator therapy before assessing whether angioplasty would be appropriate. The clinical specialists also noted that vasoactive drugs would be offered to patients who do not have easy access to a supervised exercise programme or for whom a trial of supervised exercise of 8–16 weeks did not improve the symptoms of claudication.
Are the provisional recommendations sound and a suitable basis for guidance to the NHS?	There is concern over the lack of clarity where naftidrofuryl oxalate should be used in comparison with other treatments available for claudication. The GDG are concerned that the recommendation could be interpreted as proposing naftidrofuryl oxalate as first line therapy for claudication in preference to exercise or endovascular treatment. We acknowledge this issue will be clarified in the clinical guideline and this is noted in section 4.3.2 but suggest this could be emphasised earlier perhaps as an extra sentence in section 1.1or in section 2.8.	**1.1** Naftidrofuryl oxalate isrecommended as an option for the treatment of intermittent claudication in people with peripheral arterial disease for whom vasodilator therapy is considered clinically appropriate. Treatment with naftidrofuryl oxalate should be started with the least costly licensed preparation. **2.8** A number of interventions are used to manage intermittent claudication. Stopping smoking and increasing exercise can help to reduce symptoms of claudication. People are more likely to benefit from supervised exercise programmes than from unsupervised exercise. Vasoactive drugs including cilostazol, naftidrofuryl oxalate, pentoxifylline and inositol nicotinate

		have marketing authorisations for the symptomatic relief of intermittent claudication and are considered in this appraisal. Angioplasty (that is, mechanical widening of the blood vessel) or other revascularisation (for example, arterial bypass) may be undertaken for people whose symptoms continue despite treatment. To reduce the risk of a heart attack or stroke, interventions include helping patients stop smoking, lowering cholesterol, controlling blood pressure, offering aspirin, and, in people with diabetes, controlling glycaemia.
Are there any aspects of the recommendations that need particular consideration to ensure we avoid unlawful discrimination against any group of people on the grounds of gender, race, disability, age, sexual orientation, religion or belief?	None were noted by the group.	