

Treatment Appraisal: Decision Summary

Date	20 th April 2010		
Appraisal	Bosentan (Tracleer®) in the management of digital ulcers		
Details	NETAG was requested to conduct an appraisal for the use of bosentan (Tracleer®) in the management of digital ulcers in patients with systemic sclerosis.		
Recommendation	<p>Bosentan (Tracleer®) in the management of digital ulcers is not recommended for use within NHS North East.</p> <p>Individual patients with particular circumstances may be suitable for treatment as determined via an individual funding request.</p>		
Clinical evidence summary	The group noted uncertainty regarding the clinical benefits of treatment with bosentan for digital ulcers and felt that this was compounded by the absence of publication of the key RAPIDS-2 study. The group acknowledged that all other therapies used for the treatment of digital ulcers are not licensed although most are supported by a significant evidence base.		
Cost analysis summary	The group noted the absence of evidence regarding the effect of bosentan on overall quality of life for patients with digital ulcers. The group was of the opinion that the relatively small positive effects on hand function and the relatively high cost of treatment would mean that bosentan is unlikely to meet conventional cost-effectiveness criteria when used in the management of digital ulcers.		
Financial impact	PCT	Estimated number of patients with systemic sclerosis and severe symptoms of digital ulcers	Annual cost (incl VAT)
	County Durham	5	£112,090
	Darlington	1	£22,418
	Gateshead	2	£44,836
	Hartlepool	1	£22,418
	Middlesbrough	2	£44,836
	Newcastle	3	£67,254
	North Tees	2	£44,836
	North Tyneside	2	£44,836
	Northumberland Care	3	£67,254
	Redcar & Cleveland	2	£44,836
	South Tyneside	2	£44,836
Sunderland Teaching	3	£67,254	
PbR: Excluded			
Further research or information	Patients currently receiving treatment with bosentan for digital ulcers should have the option to continue treatment until they and their clinicians consider appropriate to stop.		

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