Yorkshire and the Humber
Specialised Commissioning Group

GENERAL POLICY	Policy Ref: 15/11

Technology	Siklos (hydroxycarbamide)
Indication	**Sickle Cell Syndrome** Siklos brand of hydroxycarbamide is licensed for the prevention of recurrent painful vaso-occlusive crises including acute chest syndrome in paediatric and adult patients suffering from symptomatic Sickle Cell Syndrome.
Background:	Hydroxycarbamide is an antineoplastic medicine used mainly in the treatment of chronic myeloid leukaemia, cancer of the cervix, and essential thrombocythaemia or polycythaemia vera with a high risk for thromboembolic complications. It is also an established treatment for sickle cell disease although older preparations (e.g. Hydrea capsules [Squibb] and hydroxycarbamide medac capsules [Medac GmbH]).are not licensed for this indication. Hydroxyurea 1g tablets (as Siklos brand, Nordic) was authorised in the European Union on 29 June 2007 for the prevention of recurrent painful vaso-occlusive crises including acute chest syndrome in paediatric and adult patients suffering from symptomatic sickle cell syndrome. This commissioning policy relates to the Siklos brand of hydroxycarbamide
Commissioning position:	Siklos brand of hydroxycarbamide is **not routinely funded**.
Effective from:	22 July 2011
Summary of evidence:	This policy is based on a review of the evidence and subsequent policy developed by West Midlands SCG. This review included specific legal advice on the implications for using medicines 'off-label' when a licensed product is not routinely funded. Siklos is a branded product with the same active ingredient, hydroxycarbamide, as less expensive products that have historically been used 'off-label' to treat sickle cell disease. The substantial additional cost of Siklos branded hydroxycarbamide cannot be justified based on available clinical evidence. Legal advice supports the explicit commissioning of an unlicensed medicine when a licensed product is available.

Date approved by SCG Board:	22 July 2011
Policy to be reviewed by:	May 2019
Version:	2.0
Supersedes:	NA
Date approved by CSSG/RPSG:	5 July 2011
Responsible Officer/Contact:	Karen Billany, Head of Acute Care, NHS Hull CCG karen.billany@nhs.net
Distribution/Target Audience:	All commissioners, Yorkshire and the Humber All providers, Yorkshire and the Humber

Policy implementation guide

Technology	**Siklos (branded form of hydroxycarbamide) for sickle cell disease**
Provider Type:	Secondary and Tertiary
Current Providers:	All providers in the region
Current Service Currency:	Outpatient Not excluded from PbR tariff but, due to high-cost, may be subject to Innovation Payment Activity x Volume
Impact of change (Activity):	No anticipated change in activity
Financial Implications (PCTs):	None as hydroxycarbamide is within PbR Tariff. Siklos brand may be subject to request for Innovation (pass-through) payment but there is no indication that providers are using Siklos. Siklos brand (cost per 1 g tablet) - £16.67 Hydroxycarbamide (cost per 500mg capsule) - £0.12
Financial Implications (Providers):	None anticipated as all have indicated that they are using hydroxycarbamide 'off-label' and not using Siklos
Contracting Implications:	For local agreement.
Lead for Implementation:	CCG
Recommended Implementation Date:	TBC