SCHEDULE 2 – THE SERVICES

A. Service Specifications

Service Specification No.	03/CVDS/0038
Service	Erythroid Stimulating Agents (ESA) in patients with Myelodysplasia
Commissioner Lead	Cancer and End Of Life Clinical Commissioning Programme
Provider Lead	RBCHFT; PHFT; DCHFT.
Period	1 January 2015 to 31 December 2016
Date of Review	September 2016

1. Population Needs

1.1 National/local context and evidence base

The British Committee for Standards in Haematology (BCSH) has published guidelines on the management of adult MDS. This includes guidance on the use of ESAs for the treatment of symptomatic anaemia in IPSS low and intermediate-1 risk MDS.

Myelodysplastic syndrome (MDS) is a haematological cancer which causes anaemia in 80% of patients. The majority of these patients will require transfusions to maintain their haemoglobin. To date the only curative therapy is allogenic stem cell transplantation. Unfortunately, a median age at diagnosis of >65 years excludes this type of therapy for most patients with MDS. The aim of treatment is, therefore, supportive therapy.

The cohort of patients who are to be treated with epoetin alfa (Eprex®) (and G-CSF if necessary) is included on the Dorset's formulary as "red" drugs, are for the management of symptomatic anaemia in low risk MDS.

Long term red cell transfusions have recognised clinical hazards including red cell allo-antibodies (makes transfusions difficult) and iron overload (potentially leading to cardiac and liver impairment/failure). With time, such patients require increasing frequency of transfusion and obtain decreased length of benefit from transfusion. The quality of life of such patients is significantly reduced as well as the inconvenience the treatment causes the patient.

The practical challenges of red cell transfusion is it is a finite resource and hospitals have capacity issues around providing this service.

Erythroid stimulating agents (ESA) are given subcutaneously every 2 weeks in the patient's home. They can be given by a district nurse or self-administered. The aim is to raise the haemoglobin level such that the patient no longer requires red cell transfusions or avoids commencing them. The patient's quality of life improves and they do not develop transfusion iron overload or red cell allo-antibodies.

The Dorset Haematology NSSG has supported a case of need for certain patients with MDS to receive ESA instead of red cell transfusions.

Long term outcomes for 129 MDS patients treated with ESA+/- G-CSF were compared to untreated MDS patients (Nordic population) were:

- Median duration of response was 29 months;
- Some patients maintained a response for up to 10 years;

Estimated number of patients relevant for treatment is anticipated to be approximately 18 in the first year across the whole of Dorset.

1.2 Financial Impact

The financial impact of the service specification will be evaluated on a case by case basis. The overarching value in changing the way this small cohort of patients are treated, is to improve their quality of care and patient experience. The audit of this service, will allow commissioners to address both of these areas to understand the impact of this specification.

A number of assumptions have been made during this process:

- The number of transfusions calculated is based on an average patient receiving 2 units every 4 weeks in one admission;
- Calculation are based on anticipated worst case scenario with Eprex®;
- VAT will be applied continuously due to ongoing supply from the hospital pharmacy;
- Home delivery has not been calculated which would not incur VAT;
- Day case rate attendances have been calculated into the format;
- Telephone follow up and self-administration applied;
- Assuming current practice regarding chelation does not change.

2. Outcomes

2.1 NHS Outcomes Framework Domains & Indicators

Domain 1	**Preventing people from dying prematurely**	
Domain 2	**Enhancing quality of life for people with long-term conditions**	**√**
Domain 3	**Helping people to recover from episodes of ill-health or following injury**	
Domain 4	**Ensuring people have a positive experience of care**	**√**
Domain 5	**Treating and caring for people in safe environment and protecting them from avoidable harm**	**√**

2.2 Local defined outcomes

The overall outcome is an improved patient experience and quality of life. Evaluation is to be determined as per the audit template criteria which must be completed as part of the commissioned service.

In order for consistency and management of the audit it is recommended one clinician from within Dorset takes the lead for this area of work by co-ordinating and having general oversight of the service. This would also include regular peer to peer review of the service and its outcomes across Dorset.

In addition an annual audit report should be provided to the Dorset Medicines Advisory Group (DMAG) and the Clinical Commissioning Programme (CCP) for the duration of the pilot.

2014 Audit Template ESA MDS in Dorset Ep

3. Scope

3.1 Aims and objectives of service

The aim of the service is to improve the quality of life for patients with Myelodsyplasia; to provide them with care closer to home and improve their overall experience of care by:

- Reviewing which MDS patients were commenced on ESAs against the recommendations in the published BCSH guidelines;
- Reviewing the dose of ESAs given and whether dose escalation was required;
- Reviewing if the dosage regimen followed the published guideline;
- Documenting the response rate;
- Documenting how many transfusions (units of blood) patients required during the initial 16 weeks of therapy, if any;
- Reviewing how many patients were able to self-administer ESAs.

3.2 Service description/care pathway

Patients are identified by the clinical team within 3 months of diagnosis of symptomatic anaemia and ideally before initiating blood transfusions. Established patients within the service who score 0 or 1, should be offered EPO outside of this window.

Patients will meet the criteria stated in 3.4 inclusion criteria.

Patients will be monitored on a regular basis through MDT meetings or by a consultant led service.

The drug of choice to be prescribed for this cohort of patients for this pathway is Erythropoetin alfa – Eprex®. For those patients needing G-CSF it is anticipated Filgrastim will be used.

All requests for medication are to be processed through the hospital pharmacy on the prescription form identified. The Haematologist must email this form through to the Individual Patient Request Team (IPT) at NHS Dorset Clinical Commissioning Group Individual.requests@dorsetccg.nhs.uk, so an accurate record may be maintained of patients being treated on this pathway.

Any patient identified as receiving Eprex® where the Trust has not submitted notification through to the IPT service, will not be re-imbursed for their costs. The form will be reviewed to ensure all requests meet the approval criteria. Where the commissioners are unable to verify that the patient criteria is met, the clinician will be given the opportunity to supply further data. The commissioner may refuse to fund the patient's treatment and in this instance the Trust would be expected to maintain the patient's treatment at their cost.

ESA Prescription 2014.pdf

The prescription form is to be sent through to hospital pharmacies so they too are able to keep a record of the requests for audit purposes. This data base will be cross referenced

against specialist commissioner database to ensure financial flows for the drugs are correct and adhered to.

Each patient will be formally reviewed by the identified clinician at 6 monthly intervals.

Options are available for patients to be taught how to administer the drug at home by a qualified clinical professional and monitored on a regular basis. This improves the patient's quality of life and financial experience by not attending regularly at the hospital for treatment which they self-administer.

A haematological audit is to be provided on an annual basis to NHS Dorset Clinical Commissioning Group by all Trusts, as previously identified in 2.2. The audit is also to be submitted to the British Society for Haematology.

The service is to be operational for a period of 2 years, at which point it will be reviewed to understand the clinical outcomes for patients in detail and the financial viability of the service.

The price of blood and blood components are set annually on a national basis by NHS Blood and Transplant. The acute Trusts are charged on a cost per item basis for each blood component and added value step such as irradiation. The price of each component is based on a cost recovery basis, ie what it costs NHSBT to collect, process and routinely deliver to the Trust. The Trusts have a contract with NHSBT for Blood, Blood Components and Specialist Diagnostics and make a monthly contract payment based on a 12th of the indicative value of the contract for the year, which is then adjusted to match actual value costs. The CCG will ensure that charges for epoetin for this patient cohort are not included with those for NHS England involving other patient cohorts.

3.3 Population covered
The service is commissioned for the population who are over 18 years of age and are registered with a General Practitioner in Dorset.

3.31 Activity
Reviewing past history of the service, the criteria for admitting patients onto this pathway and in consultation with Haematology consultants the level of activity for this service is not expected to be above 20 patients per annum for the whole of the county of Dorset.

3.4 Any acceptance and exclusion criteria and thresholds
Inclusion Criteria:
Indications for use of ESA for the treatment of symptomatic anaemia in adult MDS should be in accordance with the UK MDS Guidelines 2013, found on the British Committee for Standards in Haematology (BCSH) website.

- Patients with IPSS Low and Intermediate-1 MDS, symptomatic anaemia (Hb <100) and who fulfil the criteria for a high or intermediate predictive score for response should be considered for a trial of therapy with an Erythroid Stimulating Agents (ESA).
- Patients with non-sideroblastic phenotypes, should be offered a trial of therapy with an ESA,
- Patients with sideroblastic phenotypes, should be offered a trial of therapy with an ESA plus G-CSF.

- Patients should receive a maximum trial period of 16 weeks of therapy. This should comprise 8 weeks at the starting dose of ESA+/- G-CSF and a further 8 weeks at the higher doses, if required.
- Patients achieving a complete or partial erythroid response by accepted criteria, should continue on long term therapy until the response is lost and at the minimum dose of ESAs required to maintain the response.
- The haemoglobin concentration should not be allowed to rise above 120 g/l.

Predictive response to ESA: Score 0 = 74%, Score 1 point = 23%, Score 2 points =7%

Transfusion need	Point	S-EPO	Point
<2 units RBC/month	0	<500 U/l	0
≥2 units RBC/month	1	≥500 U/l	1

Hellstrom-Lindberg, 2003

ESA should be prescribed on the Dorset NHS ESA prescription form attached at 3.2 of this specification. A copy of the initial prescription for all patients will be kept by pharmacy for audit purposes and emailed through to NHS Dorset Clinical Commissioning Group by the consultant team for validation and reconciliation of patient treatment status.

Response criteria:
Complete Erythroid Response: Achievement of Hb > 115 g/l and transfusion independence
Partial Erythroid Response: > 20 g/l increment in Hb and transfusion independence, but Hb remains < 115 g/l.

Those achieving at least PR at 16 weeks should continue until response is lost. In those who achieve a durable CR, the dose should be reduced.

The haemoglobin concentration should not be allowed to rise above 120 g/l.

Exclusion Criteria:

- Any patient who does not fit the initial inclusion criteria;
- Patients who have not responded to treatment by the end of 16 weeks.

Schedules of dosage:

- The recommended starting dose for EPO (Eprex®) is 30,000 units per week for 8 weeks. If there is no response at 8 weeks, the dose can be doubled to 60,000 units per week or 30,000 units per week for a further 8 weeks
- As this is an off label indication, patients should provide informed consent to this therapy;
- After 16 weeks, dose maintained if partial response and where there is a complete response the dose will be maintained or be reduced to ensure haemoglobin concentration does not rise above 120 g/l.

Clinical Summary Guidance

ESA Guidance for Dorset 2014.pdf

3.5 Interdependence with other services/providers

The three Acute Trusts across the county of Dorset will be working to the same service specification and work together for the purposes of this treatment and to collaborate with the audit of the service.

4. Applicable Service Standards

4.1 Applicable national standards (eg NICE)

NICE TA 142 May 08.pdf

A review of NICE technology appraisal 142 is due in November 2014. The final appraisal consultation documents states:

"1.1 Erythropoiesis-stimulating agents (epoetin alfa, beta, theta and zeta, and darbepoetin alfa) are recommended, within their marketing authorisations, as options for treating anaemia in people with cancer who are having chemotherapy.

1.2 If different erythropoiesis-stimulating agents are equally suitable, the product with the lowest acquisition cost for the course of treatment should be used."

4.2 Applicable standards set out in Guidance and/or issued by a competent body (eg Royal Colleges)

Guidelines for the Diagnosis and Management of Adult Myelodysplastic Syndromes – British Committee for Standards in Haematology. (British Journal of Haematology, Vol 120, Iss 2, pp 187-200. 2003).

4.3 Applicable local standards

Full clinical and modelling information was presented to the Dorset Medicines Advisory Group who recommended that erythropoietin alfa and G-CSF should be added to the local formulary for this indication as "red" drugs.

The DMAG members also requested to receive the results of the audit of the pilot at points 1 year and 2 years.

5. Applicable quality requirements and CQUIN goals

5.1 Applicable Quality Requirements (See Schedule 4 parts [A-D])

Not Applicable

5.2 Applicable CQUIN Goals (See Schedule 4 part [E])

Not Applicable

6. Location of Provider Premises

The Provider's Premises are located at:

- Royal Bournemouth and Christchurch Hospitals NHS Foundation Trust

Castle Lane East
Bournemouth
BH7 7DW

- Poole Hospital NHS Foundation Trust
  Longfleet Road
  Poole
  BH15 2JB

- Dorset County Hospital NHS Foundation Trust
  Williams Avenue
  Dorchester
  DT1 2JY

7. Individual Service User Placement

Not Applicable