

## Correction of anaemia in chronic kidney disease

Anaemia is an important manifestation of renal disease and is associated with increased morbidity and mortality and reduced quality of life (Thomas *et al*, 2005). Generally, anaemia management in patients with chronic kidney disease (CKD) can be divided into two phases. In the correction phase, patients diagnosed with anaemia who have not previously received treatment begin therapy with drugs which stimulate red blood cell production. Such treatment is referred to as 'de novo' treatment and the patients may be described as 'naïve' to anaemia treatment. The correction-phase of anaemia treatment can be initiated irrespective of the patient's disease (CKD) status with the aim of bringing the patient's haemoglobin (Hb) level into the target range recommended in expert guidelines and then maintaining it within this range. Once stabilised, the 'maintenance' phase of treatment can begin.

### Anaemia correction - goals

- Evidence based expert guidelines recommend that Hb levels should be assessed in any patient with CKD regardless of the stage of CKD or the patient's age, race, gender or existence or not of various co-morbidities (KDOQI, EBPG).
- Treatment guidelines regarding the use of drugs which stimulate red blood cell production (see below) advise that Hb levels are corrected to and maintained within a specific range of 11 g/dL to 13 g/dL. In the US, the guidelines caution when intentionally maintaining haemoglobin >13 g/dl (KDOQI/EBPG). Depending on the products and the countries, the approved Hb target range may vary.
- Guidelines recommend that Hb levels should be corrected within 4 months (EBGP).
- European Best practice Guidelines (EBPG) recommends an Hb increase of 1-2 g/dL per month with Hb levels monitored every 2-4 weeks during the correction phase.
- When correcting Hb levels in CKD patients, going above the maximum target range may also result in unnecessary drug use and associated costs (Clyne *et al*, 2006).
- The highest rates of hospitalization and mortality have been observed in patients in whom haemoglobin levels remain below 11 g/dL (Gilbertson *et al*, 2006). Therefore, once the haemoglobin level has been corrected, it is recommended by current guidelines that Hb levels be maintained within the target range.

## Anaemia Treatments – the ‘Correction’ Phase

Currently available drugs for treating renal anaemia are summarised in the table below:

ESA	Approval status		Frequency of dosing
	U.S.	Europe	
Epoetin alfa	Epogen® (Amgen) – dialysis patients only, Procrit® (Ortho Biotech) – Pre-dialysis patients only	Eprex® (Janssen-Cilag)	3 times per week IV and SC
Epoetin beta	Not approved for use in the U.S.	NeoRecormon® (Hoffmann-La Roche)	3 times per week IV and SC.
Darbepoetin alfa	Aranesp® (Amgen)	Aranesp® (Amgen) Nespo® (Dompe Biotech, SPA)	Once weekly IV and SC; alternatively once every two weeks may be administered only in pre-dialysis patients (SC) in EU.

### MIRCERA®

- Roche’s MIRCERA®, the first Continuous Erythropoietin Receptor Activator (C.E.R.A.) anti-anaemia drug represents a new class of agents. Its activity at the receptor sites involved in stimulating red blood cell production is different from that observed with the first epoetin drugs. The distinct molecular interaction of MIRCERA is believed to play an important role in providing targeted, stable and sustained control of anaemia.
- In previously untreated CKD patients with renal anaemia, MIRCERA achieves approximately 95% Hb correction response rate (MacDougall *et al*, 2006) with a simple initial dosing schedule of twice a month.
- Roche filed license applications for MIRCERA with regulatory authorities in the European Union and the United States in April 2006 seeking approval for the treatment of anaemia (correction and maintenance) associated with CKD in patients on dialysis and not on dialysis.

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## References

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