

Methoxy polyethylene glycol-epoetin beta (Mircera[®]) Protocol

Methoxy polyethylene glycol-epoetin beta (Mircera[®]) ICD 10 code D63.1
Anemia in chronic kidney disease

Purpose: To provide optimal management of ESRD related anemia in dialysis patients

Hemoglobin Target Goal: 10.0-11.0 g/dL

Methoxy polyethylene glycol-epoetin beta Dosing:

Doses are based on estimated dry weight and rounded to the following steps:

| Step | Dose |
|------|--|
| 1 | 30 mcg every <i>four</i> weeks |
| 2 | 50 mcg every <i>four</i> weeks |
| 3 | 30 mcg every two weeks |
| 4 | 50 mcg every two weeks |
| 5 | 60 mcg every two weeks (30 mcg + 30 mcg) |
| 6 | 75 mcg every two weeks |
| 7 | 100 mcg every two weeks |
| 8 | 150 mcg every two weeks |
| 9 | 200 mcg every two weeks |

Table 1

1. Methoxy polyethylene glycol-epoetin (Mircera[®]) will be increased and decreased in 1-step or 2-step increments, based on scale above.
2. Mircera[®] will be administered IV to in-center hemodialysis patients, and SQ to home dialysis patients.
3. Mircera[®] ceiling is 200 mcg every two weeks (or 3.0 mcg/kg/2 weeks, whichever is lower). Orders above 200mcg every two weeks require facility medical director or CMO approval.

Initiating Mircera[®] for new patients or ESA naïve patients

For new patients or established patients who have not received an ESA within the last 3 months, initiate as follows:

1. Iron repletion per iron standing orders
2. AND
 - a. If Hgb < 10 g/dL, then start Mircera[®] at 0.6 mcg/kg/2 weeks, and round down to closest step per Table 1 but no less than 30 mcg every 2 weeks (Step 3).
 - b. If Hgb 10.0-10.4 g/dL, then start Mircera[®] at 30 mcg every 2 weeks (Step 3).
 - a. If Hgb >= 10.5 g/dL, then do not start Mircera[®] until patient meets criteria.

Patient Name _____

NKC# _____

Mircera® Dosing Adjustment

1. Titrate Mircera® per the following table for patients who have a Mircera® order and had not been changed in the last 4 weeks:

| <u>Mircera® Dosing Adjustment</u> | |
|--|---|
| Hgb decreased by greater than or equal to 0.5 g/dL since last dose change | |
| Hgb (g/dL) | Step Dose Change |
| Less than 10 | 2 step dose increase |
| 10.0-10.9 | 1 step dose increase |
| 11-11.9 | No Change |
| Hgb increased/decreased by less than 0.5 g/dL since last dose change | |
| Hgb (g/dL) | Step Dose Change |
| Less than 9.5 | 2 step dose increase |
| 9.5-9.9 | 1 step dose increase |
| 10.0-10.4 | 1 step dose increase, if Hgb decreased; do not change if Hgb increased or stayed the same |
| 10.5-11.4 | No change |
| 11.5-11.9 | 1 step dose decrease; if patient is on Step 1, do not HOLD |
| Hgb increased greater than or equal to 0.5 g/dL since last dose change | |
| Hgb (g/dL) | Step Dose Change |
| Less than 10 | 1 step dose increase |
| 10-10.4 | No Change |
| 10.5-11.9 | 1 step decrease; if patient is on Step 1, do not HOLD |
| Hgb (g/dL) | Dose Change |
| Greater than or equal to 12 g/dL | Hold Mircera; check Hgb at next redraw for home dialysis patients, and every week for in-center patients. |
| If Hgb is increased or decreased at least 1.0 g/dl since the last Hgb level; recheck Hgb within next 2 dialysis treatments for in-center HD and at next redraw for home patients. Follow the algorithm based on the results of the recheck, e.g., if the value remains the same as the first draw, then follow the algorithm for no change. | |

Table 2

2. Do not change Mircera® dose more frequently than every 4 weeks EXCEPT:
 - a. If Hgb falls from above 10 g/dL to less than 10 g/dL, increase dose after 2 weeks.
 - b. If Hgb is already less than 10 g/dL and drops greater than 0.5 g/dL, increase dose after 2 weeks.
 - c. If Hgb >= 12 g/dL, hold Mircera® and check Hgb every week for in-center patients, and at next redraw for home dialysis patients. Resume Mircera® with 1-step decrease as soon as Hgb is < 11.8 g/dL and last dose was administered 2 weeks ago or more. If Hgb remains >= 12 g/dL for more than 2 months, return to regular Hgb testing policy.

Conversion from darbepoetin or erythropoietin to Mircera®

1. When a patient with a darbepoetin (Aranesp) or erythropoietin order switches to Mircera®, discontinue darbepoetin (Aranesp) or erythropoietin order.
2. Convert darbepoetin or erythropoietin to appropriate dose of Mircera®, per conversion dose chart below. Convert to Mircera® when the next ESA dose is due.

3. If ESA is on HOLD from another protocol, wait until Hgb is less than 11.8g/dl, then convert ESA as follows: See Table 3 or 4 to convert previous ESA dosing to Mircera[®] Step, then see Table 1 and decrease 1 Step.

| Erythropoietin to Methoxy Polyethylene Glycol Epoetin-beta Conversion Dose Chart | | |
|---|---------------------------|---------------|
| Epogen Dose (U) per week - total | Mircera [®] Dose | |
| | Dose (mcg) | Frequency |
| < 2000 | 30 | Every 4 weeks |
| 2000 - < 3000 | 50 | Every 4 weeks |
| 3000 - < 5000 | 30 | Every 2 weeks |
| 5000 - < 8000 | 50 | Every 2 weeks |
| 8000 - < 11,000 | 60 | Every 2 weeks |
| 11,000 - < 18,000 | 75 | Every 2 weeks |
| 18,000 - < 27,000 | 100 | Every 2 weeks |
| 27,000 - < 42,000 | 150 | Every 2 weeks |
| >= 42,000 | 200 | Every 2 weeks |

Table 3

| Darbepoetin (Aranesp) to Methoxy Polyethylene Glycol Epoetin-beta Conversion Dose Chart | | |
|--|---------------------------|---------------|
| Darbepoetin Dose (mcg) per week - total | Mircera [®] Dose | |
| | Dose (mcg) | Frequency |
| < 10 | 50 | Every 4 weeks |
| 10 - <20 | 30 | Every 2 weeks |
| 20 - <30 | 50 | Every 2 weeks |
| 30 - < 40 | 60 | Every 2 weeks |
| 40 - < 50 | 75 | Every 2 weeks |
| 50 - < 60 | 100 | Every 2 weeks |
| 60 - < 100 | 150 | Every 2 weeks |
| >= 100 | 200 | Every 2 weeks |

Table 4

Labs:

Draw CBC per routine lab orders.

Suzanne Watnick, MD

Physician Name (Please Print)

Physician signature

Date

Patient Name _____ **NKC#** _____