Modification of Diet in Renal Disease Study

DOCUMENTATION OF BLOOD PRESSURE TREATMENT FORM

This form is to be completed at B3, F6, F12, and every six months thereafter for each patient. This form will also be completed at any monthly visit when a patient's blood pressure regimen has changed since the previous visit.

QUESTION #	INSTRUCTIONS
4c	This form should only be completed at clinic study visits, so the visit number codes should always be whole numbers.
5	Complete the form at every visit for which the blood pressure regimen changed. If it changes at the visit, complete the form at the visit. If it changes between two visits, complete the form at the second visit. If the regimen changes more then once between two visits, enter the date of the most clinically important change or, if all of the changes are equally important, enter the date of the most recent change.
6	If the form is completed at, for an example, an F3, then the routine F6 form (unless NEW changes have occured) should indicate a 2.
8	Please rank using your study team's best clinical judgement. If medication side effects are unknown or not applicable, enter 99 for questions a-e then proceed to question 9.
10 c-d	The answers to these questions are based upon the home blood pressure monitoring logs that each patient should bring with them to the clinic visit and are filled out only if the patient performs home blood pressure monitoring.

MDRD

Modification of Diet in Renal Disease Study
Documentation of Blood Pressure Treatment Form

This form is to be completed at B3, F6, F12, and every six months thereafter for each patient.

This form will also be completed at any monthly visit when a patient's blood pressure regimen has changed since the previous visit.

FORM # 5 2

1. Patient Identification Number ..... ___ ___ ___ ___ ___ ___
2. Patient Name Code ..... ___ ___ ___ ___
3. Clinical Center ..... ___ ___
4. a. Date of Visit: ..... ___ ___/ ___ ___/ ___ ___
   b. Visit Type: ..... ___
   c. Visit Number: ..... ___ ___ . ___
5. Date blood pressure regimen changed ..... ___ ___/ ___ ___/ ___ ___
   If changed more than once, identify first date changed.
   If not changed, enter date of visit again.
6. Reason this form is being completed: ..... ___
   1 = Change in blood pressure regimen done at or between any MDRD visits, including B3, F6, or F12, etc.
   If so, please be sure the medication change is noted appropriately on the Form 5.
   If multiple changes occurred, make sure Form 5 reflects current medications.
   2 = There is no change in the blood pressure regimen at this time, but this is a B3, F6, or F12, etc. visit.
7. Reason for change(s) in medication(s): ..... ___

   1 = Not Effective for BP Control
   2 = Possible Side Effects
   3 = Probable Side Effects
   4 = Not Effective as well as Side Effects
   5 = Other (Specify) (20 characters) _____
   6 = Not Applicable, no medications were discontinued or reduced or added.

7 MAP ↓ goal 8 MAP ↓ goal with side eff

8. If medications were changed due to side effects (2, 3, or 4 above), what possible or probable side effects of medication is the patient experiencing? (See Side Effect Profile Option List on page 2.) (**)
   a. Primary side effect noted ..... ___ ___
   b. Secondary side effect noted ..... ___ ___
   c. Third most important side effect noted ..... ___ ___
   d. Fourth most important side effect noted ..... ___ ___
   e. Fifth most important side effect noted ..... ___ ___

** If medication side effects are unknown or not applicable, enter 99 for questions a-e then proceed to question 9.

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SIDE EFFECT PROFILE OPTION LIST

General:
1. Orthostatic Symptoms
2. Syncope
3. Peripheral Edema
4. Headache
5. Drowsiness/Sedation
6. Fatigue/Tiredness
7. Insomnia
8. Vivid Dreams/Nightmares
9. Sexual Dysfunction
10. Depression
11. Numbness/Tingling of Extremities

Gastrointestinal:
12. Dry Mouth
13. Nausea/Vomiting
14. Anorexia
15. Abdominal Gas
16. Constipation
17. Diarrhea
18. Dysgeusia
19. Liver Dysfunction

Cardiac/Respiratory/Vascular:
20. Cough
21. Dyspnea
22. Wheezing
23. Palpitations
24. Exacerbation of CHF
25. Worsening Claudication
26. Coldness of Extremities

Dermatologic:
27. Rash
28. Pruritus
29. Flushing
30. Alopecia
31. Hypertrichosis
32. Excess Perspiration
33. Angioneurotic Edema

Metabolic/Endocrine:
34. Worsening Glucose Tolerance
35. Worsening Lipid Status
36. Hypokalemia
37. Hyperkalemia
38. Hyperuricemia/Gout
39. Muscle Cramps

Miscellaneous:
40. Anemia
41. Drug-Induced Lupus
42. Pericardial Effusion
43. Gynecomastia

Other:
44. Other Side Effect
45. Bradycardia

None:
99. No Side Effect/Unknown/Not Applicable

9. a. Physician assessment of patient compliance with prescribed blood pressure regimen: ....___
   1 = Fully Compliant
   2 = Partially Compliant
   3 = Non-Compliant
   4 = Don't Know/No assessment made

   b. Patient assessment of satisfaction with blood pressure regimen and goal: ....___
   1 = Completely Satisfied
   2 = Troublesome Side Effects or Symptoms of Low BP but Tolerable
   3 = Intolerable Side Effects or Symptoms of Low BP
   4 = Other (Specify) _____

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10. Home Blood Pressure Monitoring
    a. Patient performs home blood pressure monitoring (1 = yes, 2 = no) ..... ___

    If 2 = no, skip to item 101.

    b. Compared to official study readings, home BP readings are ..... ___
       1 = In the same range as clinic readings.
       2 = Usually higher than clinic readings.
       3 = Usually lower than clinic readings.
       9 = Unknown

    c. Does this patient have persistent low BP symptoms (action item levels) based on non-MDRD visit pressures? (1 = yes, 2 = no) ..... ___

    d. Does this patient have persistent high blood pressure (action item ranges) based on non-MDRD visit pressures? (1 = yes, 2 = no) ..... ___

101. Date this form completed ..... ___ ___/ ___ ___/ ___ ___

102. Certification number of person filling out this form ..... ___ ___ ___ ___ ___

103. Date form entered ..... ___ ___/ ___ ___/ ___ ___

104. Certification number of data entry person ..... ___ ___ ___ ___ ___