

Form 031

FOLLOW-UP DRUG SECTION

1 1, 2, 3

Record information on BHAT study medication and known beta-blockers. At least one entry must be made at every BHAT interview or interim visit. If dose has not been changed, use date of interview or interim visit, entry code 04 and record current dose.

2 3 4
Patient ID # 4, 5 6, 7, 8, 9, 10 11, 12

5
Acrostic 13, 14, 15, 16, 17, 18

Date of interview 11 44, 45 46, 47 48, 49
month day year

NOTE: Date in field 11 matches date in field 11 of BH08, BH11, BH12 or BH16

See above for drug codes, entry code, sign/symptom and reason codes

12 13 14 15 16 17 18 19
Month Day Year Drug Code Entry Code Major Reason for change in dose Other Total Daily Dose (mg.)
50, 51 52, 53 54, 55 56, 57 58, 59 60, 61, 62 63, 64, 65 66, 67, 68 69, 70, 71 72, 73, 74, 75 76

(specify drug) (specify sign/symptom or reason)

NOTE: Each line of this page produces a separate masterfile record consisting of fields 1-19.

(specify drug) (specify sign/symptom or reason)

(specify drug) (specify sign/symptom or reason)

(specify drug) (specify sign/symptom or reason)

(specify drug) (specify sign/symptom or reason)

(specify drug) (specify sign/symptom or reason)

(specify drug) (specify sign/symptom or reason)

(specify drug) (specify sign/symptom or reason)

(specify drug) (specify sign/symptom or reason)

6 EDIT STATUS 19,20
7 BATCH NUMBER 21-28

8 DATE RECEIVED 29-34
9 UPDATE NUMBER 35-37

10 DATE LAST PROCESSED 38-43

Drug Codes:
 01 Inderal
 02 Betaloc
 03 Blocadrin
 04 Lopressor
 05 Timpotic (Timolol eye drops)
 06 Timolol oral medication
 07 Corgard (Naldolol)
 08 other "Beta Blocker"
 77 BHAT medication

Entry Codes:
 01 Drug started
 02 Dose changed
 03 Drug stopped
 04 No dose change
 05 Still off BHAT medication

BH 31

Reason Code for Dose Change

- 001 Faintness or light-headedness when patient stood up quickly (or at other times)
- 002 Problem with heart beating fast or skipping beats
- 003 Blacking out or losing consciousness
- 004 Frequent depression that interfered with work, recreation, or sleep
- 005 Unusual tiredness, fatigue or weakness during ordinary activities
- 006 Frequent nightmares or vivid dreams
- 007 Hallucinations
- 008 Blurred vision
- 009 Recurrent insomnia or problems with waking up too early
- 010 Recurrent nausea and/or vomiting
- 011 Recurrent abdominal pain or cramping
- 012 Recurrent diarrhea
- 013 Recurrent constipation
- 014 Recurrent bronchospasm (wheezing in the chest)
- 015 Recurrent muscle cramps
- 016 Disorientation in time and space
- 017 Frequent or severe intermittent claudication
- 018 Bronchial asthma or chronic lung disease requiring therapy
- 019 "Brittle" insulin-dependent diabetes mellitus
- 020 Wolff-Parkinson-White syndrome
- 021 Mobitz type II or complete A-V block
- 022 On MAO-inhibitors or amphetamines
- 023 Congestive heart failure
- 024 Cardiogenic shock
- 025 Valvular heart disease
- 026 Significant angina pectoris
- 027 Has undergone cardiac surgery
- 028 Has permanent pacemaker
- 029 Chest wall trauma
- 030 Has life-threatening illness other than CHD
- 031 Scheduled for or very likely to undergo cardiac surgery
- 032 Adherence to the study protocol has proved to be especially difficult
- 033 Unable (physically or psychologically) to cooperate with study
- 034 Hypertension
- 035 Hypotension
- 036 Stroke
- 037 Undergoing procedure likely to lead to unblinding
- 038 Scheduled for surgery (other than cardiovascular)
- 039 Dryness of eyes
- 041 Sign/symptom decreased in severity or disappeared or procedure completed
- 042 First degree heart block or Mobitz I
- 043 Significant sinus bradycardia
- 044 Death
- *045 Physician will not allow increase to 60 or 80
- 046 Patient not yet on 40 mb., so cannot go to 60 or 80
- 047 New or extended myocardial infarction
- 048 Coronary arteriography
- 049 High fever
- 050 Flushing or hot flashes
- 051 Impotence
- 052 Other medical procedure
- 053 ECG changes
- 054 Liver enzyme elevation, liver disease
- 055 Nervousness
- 056 Diabetes, hypoglycemia
- 057 Cancer
- 058 Hands and/or feet cold or burning and prickling
- 059 Dry mouth
- 060 Sudden loss of hair
- 061 Rash or itching

- 062 GI bleeding
- 063 Pulmonary problems
- 064 Unblinding of study drug → Complete form BH
- 065 Urinary frequency
- 066 Aphasia
- 067 Positive stress test
- 068 Severe coronary artery disease
- 069 Significant ventricular arrhythmia
- 070 Slow atrial fibrillation
- 071 Patient refused some or all medication
- 072 Hospital personnel forgot to administer
- 073 Physician increased or withheld some or all of medication, physician's clinical judgement
- **074 Left hospital before receiving full dose
- 075 Not all prescribed medication was available to be given to the patient
- 076 Order prescription or patient interpretation incorrect
- 077 Hospital personnel gave too much medication
- 078 Correction of error in order, prescription or patient interpretation
- 079 Patient reconsidered and will participate
- 080 Shortness of breath
- 082 Generally feeling bad
- 083 Anemia
- 084 Patient not available
- 085 Vascular occlusion
- 086 Heavy sweating
- 087 Headache
- 088 Following protocol
- 089 Patient consistently forgot
- 091 Drop in heart rate
- 092 Phlebitis
- 093 Hematuria
- 094 Coronary artery spasm
- 095 Symptoms appeared unrelated to drugs
- 096 Moving away from any Clinical Center
- 097 Stuffy nose
- 098 Physician will not restart or raise dosage because of initial reason though condition is no longer present.
- 099 Misunderstanding of protocol
- 100 Puffy eyelids
- 101 Suspected C.H.F. (fine basilar rales)
- 102 Rapid atrial fibrillation
- 103 Hypoprothrombinemia
- 104 Addison's Disease
- 105 Step-up recommendation to 80 mg. t.i.d. not received on time
- 106 Slurred speech
- 107 Glaucoma
- 108 Pericarditis
- 109 Thrombocytopenia
- 110 Tachycardia
- 111 Numbness hands and/or feet
- 112 Changing non-study beta-blocker for better compliance
- 113 Ventricular aneurysm
- 114 Cannot swallow
- 115 Left ventricular dysfunction
- 116 Hypothyroidism
- 117 Percutaneous transvenous coronary artery dilatation
- 118 Esophagus spasm

Reason Code for Dose Change, Continued

- 119 Chest distress (atypical for angina)
- 120 Documented coronary artery narrowing or ischemia without angina
- 121 Cardiac Arrest
- 122 Peripheral edema
- 123 Tremors
- 124 Faint Pulse