

Diabetes Prevention Trial - Type 1 ENCOUNTER FORM

Complete this form each time an encounter (either phone contact or a clinic visit) occurs with the subject for any of the 'Reasons for encounter' listed below.

Subject ID #:

Subject Initials:
F M L

Date: / /
M M D D Y Y

Date of Visit: / /
M M D D Y Y

Name of person completing form (please print): _____

All Subjects:

1. Reasons for encounter (check all that apply):

- Baseline Visit (Testing Location Code (TLC) for reimbursement:)
- Routine follow-up visit per protocol* (every 6 months) (TLC for reimbursement:)
- Treatment adjustment (for Parenteral Antigen/Experimental Treatment subjects only)
- Suspected adverse event (*submit adverse event form)
- Follow-up call to '800' complications line (*submit adverse event form)
- Counseling/education
- Pregnancy (*submit pregnancy form)
- Symptoms of diabetes
- Study end visit (TLC for reimbursement:)
- Other (specify, _____)

* Please note that only one Routine follow-up Visit will be reimbursed each 6-month period. If multiple EI forms indicating a follow-up visit was completed are received in DMU within the projected time window around the scheduled 6-month visit, the form with the earliest date will be used to determine reimbursement.

2. Do you suspect that the subject is taking any of the following?

1=No 2=Yes 3=Don't Know

- Insulin not called for by DPT-1 protocol
- Nicotinamide
- Steroids
- Immunosuppressive medication

If yes to any, explain: _____

3. CHECK	ACTIONS
<input type="checkbox"/>	Blood Glucose Test Strips Dispensed _____
<input type="checkbox"/>	Home Glucose Profile Forms Dispensed

Complete only for Parenteral Antigen/Experimental Treatment Group subjects:

Initial Insulin Dose: 0.25 units/kg/day Humulin-U divided into two equal doses

Weight (kg) = X 0.25 units/kg/day = . units/day ÷ 2 = . units/dose

Date of initiation of subcutaneous treatment : / /
M M D D Y Y

OR

Current Insulin Dose: 0.xx units/kg/day Humulin-U divided into two equal doses

Weight (kg) = X 0.xx units/kg/day = . units/day ÷ 2 = . units/dose

1. Have you prescribed a change in insulin regimen or dose since the subject's last visit?
 1=No 2=Yes If Yes, reason for change: _____

2. Since the last scheduled protocol visit (i.e. 6 months ago) how many injections/doses has the subject missed? (If unknown, enter 999) (If ≥14 injections or ≥ 7 doses of oral medication, subject is considered non-compliant. Submit II Form.)
 If ≥14 or ≥7, explain why: _____

3. Date of last subcutaneous insulin injection: / /
M M D D Y Y

4. CHECK	ACTIONS
<input type="checkbox"/>	New Vial(s) of Humulin-U / New bottles of Medication Dispensed
<input type="checkbox"/>	Old Vial(s) of Humulin-U / Old bottles of Medication Returned; Volume/vial _____ (cc)
<input type="checkbox"/>	Syringes Dispensed _____