The Antiretroviral Pregnancy Registry

Instructions for Completing the REGISTRATION FORM

General Guideline: Date format should always be entered as DD/MMM/YYYY

Patient (Log) ID: The Registry assigned Log ID number.

Date patient first seen during this pregnancy: Provide the date first seen in DD/MMM/YYYY format.

1. Maternal Information
   1.1 Clinical Study: Indicate if the patient is participating in a clinical study by checking “Yes”, “No”, or “Unknown”.
       • If no, move to Subsection 1.2
       • If yes, provide the study protocol number and indicate whether the study was conducted in pregnant women by checking “Yes” or “No”
   1.2 Last Menstrual Period (LMP): Provide the start date for the LMP in DD/MMM/YYYY format.
   1.3 Corrected Estimated Date of Delivery (CEDD): Provide the CEDD based on the 20 week prenatal test, especially if this is the date being used to calculate gestational age for medication exposures and outcome. If a date is entered here, prenatal test name(s) and date(s) must be entered in Section 2.1.
   1.4 Patient Age: Provide age of the pregnant woman at time of conception.
   1.5 Race: Check the appropriate box for the pregnant woman’s race.

2. Prenatal Tests
   2.1 Prenatal Test Done: Indicate if a prenatal test was done by checking “Yes”, “No”, or “Unknown”.
       • If no, move to Section 3: Clinical Indicators.
       • If yes, provide the date in DD/MMM/YYYY format, or the gestational age, the prenatal test was performed and the name of the prenatal test (i.e., Ultrasound, Amniocentesis, MSAFP). If “Other”, specify the prenatal test performed.
   2.2 Evidence of a Structural Defect: Indicate if a structural defect(s) was identified on a prenatal test by checking “Yes”, “No” or “Unknown” by each prenatal test done.
       • If no, move to Section 3: Clinical Indicators.
       • If yes, specify the structural and/or chromosomal defect(s).

3. Clinical Indicators (at the START of pregnancy)
   3.1 Indication for ARV (Check all that apply)
   3.2 Earliest CD4 + T-cell Categories (in this pregnancy): Check the appropriate range for the counts as they were as close to the beginning of the pregnancy (not applicable should be marked if the patient is not HIV infected).
   3.3 Worst Disease Severity Indicator (by history):
       • HIV: Check the appropriate category for the worst disease severity experienced by the patient at any time since becoming infected (not applicable should be marked if the patient is not HIV infected). Clinical categories A, B and C are as defined by the CDC [www.cdc.gov/mmwr/preview/mmwrhtml/00018871.htm]
         • Category A: Consists of one or more of the CDC defined Category A conditions in a person with documented HIV infection. Conditions in Categories B and C must not have occurred.
         • Category B: Consists of symptomatic conditions in an HIV-infected person not included in Category C and meeting at least one of the two Category B conditions. For classification purposes, someone previously treated for a Category B condition but who is now asymptomatic should be classified in Category B.
         • Category C: Includes the clinical conditions listed in the AIDS surveillance case definition. For classification purposes, once a Category C condition has occurred, the person will remain in Category C.
         • Category D: CD4 <200 cells/µL
       • Hepatitis: Check the appropriate category for the worst disease severity experienced by the patient at any time since becoming infected (not applicable should be marked if the patient does not have hepatitis).
The Antiretroviral Pregnancy Registry

Instructions for Completing the Antiviral Therapy During Pregnancy Form

- **Med Code:** Indicate the code number from the list provided. If a drug is not listed, provide the name of the drug.
- **Total Daily Dose:** Provide the total daily dose with units (e.g., 80 mg, 2 tabs, 2 mg/kg/hr, etc.).
- **Route:** Provide the code “1” for oral, “2” for IV, and “3” for subcutaneous (sub-Q).
- **Pt taking Meds at Conception?:** “1” if yes at conception, “2” if during pregnancy, “3” if unknown.
- **Date Treatment Began or Gestational Age Course Began:**
  - Provide start date in **DD/MMM/YYYY** format, OR
  - Provide gestational age course began. If gestational age is known, check the calculation source: LMP or Corrected EDD. If CEDD is checked, prenatal test name(s) and date(s) must be entered on page 1 Section 2.1.
- **Date Treatment Stopped or Ongoing:**
  - Provide date or gestation week treatment stopped in **DD/MMM/YYYY** format, OR
  - Check “Ongoing” if treatment continues following outcome of pregnancy.

Please write “unk” or “N/A” on the forms if any information is unknown or not applicable.

The Registry is not designed to monitor all types of events that might occur during pregnancy, labor and delivery, or other neonatal or post-natal events other than defects. If such events occur the provider is encouraged to contact the manufacturer of the individual drug and/or the FDA. FDA can be reached by faxing the information to 800-FDA-0178 or at http://www.fda.gov/Safety/MedWatch/default.htm

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**Phone Contact:**
US/Canada Phone: 800-258-4263 (Toll Free)
UK, Germany, France Phone: 00800-5913-1359 (Toll Free)
International Phone:+32-2-714-5028 (Europe)

**Address:**
301 Government Center Drive, Wilmington, NC 28403

**Internet:**
www.APRegistry.com

Revised (June 2019)
**ANTIRETROVIRAL PREGNANCY REGISTRY**

**REGISTRATION FORM**

Fax to: +1-800-800-1052 (US, Canada)  
+1-910-256-0637 (International) or +32-2-714-5024 (Europe)  
8000-5812-1658 (UK, Germany, France)  
800-892-1472 (Brazil)  
Email to: SM_APR@APRegistry.com

FOR OFFICE USE ONLY  (1)

**Registry Patient ID ______________ HCP ID ______________**

Prospective ☐ Retrospective ☐ 100% Provider ☐  
Phone ☐

Registry date of notification ____________  
DD  MMM  YYYY

**Patient (Log) ID:** ________________  
Registry assigned ID number or Sponsor MCN

**Country of report origin_____________ State (U.S. only)__________**  
Date patient first seen during this pregnancy or Sponsor date of notification of pregnancy:  
Date: ____________  
DD  MMM  YYYY

1. **MATERNAL INFORMATION**

1.1 Is the patient enrolled in a clinical study? (treatment or observational study)  
☐ Yes  ☐ No  ☐ Unknown  
If yes, provide the protocol number

1.2 Last Menstrual Period DD  MMM  YYYY

1.3 Corrected EDD DD  MMM  YYYY (e.g., by ultrasound)

1.4 Patient Age: ____________  
(at conception)

1.5 Race:  
☐ White  ☐ Black  ☐ Hispanic  ☐ Asian  ☐ Other (specify) _______________

2. **PRENATAL TESTS**

2.1 Was a prenatal test done?  
☐ No (go to section 3)  
☐ Yes (complete below and question 2.2)  
Date OR Gestational Age when test(s) done:

(✓) test(s):  
☐ Ultrasound _______________________________ date  
☐ Ultrasound _______________________________ date  
☐ Amniocentesis ____________________________ date  
☐ Cystic Fibrosis Mutation Analysis____________________ date  
☐ Fetal Echo _______________________________ date  
☐ First Trimester Screen ______________________ date  
☐ MSAFP/serum markers _____________________ date  
☐ Nuchal Translucency _______________________ date  
☐ Other (specify): ______________________________ date  
☐ Unknown (go to section 3)

2.2 Is there evidence of a structural defect from one or more of these prenatal tests?  
☐ Yes  ☐ No  ☐ Unknown. If yes, Specify defect ___________________

3. **CLINICAL INDICATORS** (at the **START** of pregnancy)

3.1 Indication for ARV (✓ all that apply):  
☐ HIV Infected  
☐ HIV Non-Infected  
☐ Post-Exposure Prophylaxis (PEP)  
☐ Pre-Exposure Prophylaxis (PrEP)  
☐ Hepatitis B  
☐ Hepatitis C

3.2 Earliest CD4+ T-cell Categories (in this pregnancy):  
☐ > 500 cells/µL  
☐ 200-499 cells/µL  
☐ <200 cells/µL  
☐ Not applicable

3.3 Worst Disease Severity Indicator (by history):

HIV  
☐ A. Asymptomatic, acute (primary) HIV or PGL (persistent generalized lymphadenopathy)  
☐ B. Symptomatic, not (A) or (C) conditions  
☐ C. Other AIDS-indicator conditions  
☐ D. CD4 <200 cells/µL  
☐ E. Not applicable

Hepatitis  
☐ A. Compensated liver disease (Pugh score <7)  
☐ B. Decompensated liver disease (Pugh score ≥7)  
☐ C. Not applicable

For additional descriptions of categories refer to the 1993 CDC revised classification system, December 1992 issue of MMWR

Complete applicable information on: **ANTIVIRAL THERAPY DURING PREGNANCY Form**

**HEALTH CARE PROVIDER INFORMATION**

Name ________________________________  
Address ________________________________  
Specialty ________________________________  
Phone ________________________________  
Alternate Contact ________________________  
Fax ________________________________  
Email ________________________________  
Provider’s Signature ________________________  
Date ____________  
DD  MMM  YYYY
4. ANTIRETROVIRAL THERAPY EXPOSURES

4.1. In the following table, describe each course or change in route for each applicable therapy taken DURING PREGNANCY. Any antiretroviral injections administered during pregnancy should be listed separately on a new row. All registered therapies are listed in section 4.2. If the therapy is missing from list, please specify medication name and manufacturer in table below.

<table>
<thead>
<tr>
<th>Course</th>
<th>Med. Code (1-60)</th>
<th>Blinded therapy?</th>
<th>Total Daily Dose</th>
<th>Route</th>
<th>Pt Taking Med. Prior to Conception?</th>
<th>Date Treatment Course Began (DD-MMM-YYYY)</th>
<th>Date Treatment Stopped (DD-MMM-YYYY), Gestational Week Course stopped OR Ongoing following delivery?</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td>1 = Yes 2 = No 3 = Unknown</td>
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<td></td>
</tr>
</tbody>
</table>

Calculation Source (FOR OFFICE USE ONLY)
- LMP
- corrected EDD
4.2 Use the medication codes below for antiviral medication taken during pregnancy (see section 4.1). If not coded, Specify medication name and manufacturer in table above.
| Page 3 of 3 |

Complete as much of this page as applicable at Registration. A copy of this form will be sent to you in the expected month of delivery for completion.

**Patient Log ID: ___________________** *(The Registry assigned, non-patient identifying patient ID or Sponsor MCN)*

<table>
<thead>
<tr>
<th>#</th>
<th>Drug Name</th>
<th>Manufacturer</th>
</tr>
</thead>
<tbody>
<tr>
<td>20.</td>
<td>Adefovir dipivoxil (HEPSERA®, ADV) – Gilead</td>
<td>20.4</td>
</tr>
<tr>
<td>20.1</td>
<td>Adefovir dipivoxil generic – SigmaPharm</td>
<td>20.5</td>
</tr>
<tr>
<td>20.2</td>
<td>Adefovir dipivoxil generic – Apotex</td>
<td>20.6</td>
</tr>
<tr>
<td>20.99</td>
<td>Adefovir dipivoxil (unknown manufacturer)</td>
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<tr>
<td>21.</td>
<td>Entefuviride (FUZEON®, T-20) – Roche (no longer partic.)</td>
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</tr>
<tr>
<td>22.</td>
<td>Atazanavir (REYATAZ®, ATV) – BMS</td>
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</tr>
<tr>
<td>22.1</td>
<td>Atazanavir generic – Aurobindo</td>
<td>20.99</td>
</tr>
<tr>
<td>22.2</td>
<td>Atazanavir generic – Cipla</td>
<td>21.0</td>
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<td>22.3</td>
<td>Atazanavir generic – Amneal</td>
<td>30.1</td>
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<td>22.4</td>
<td>Atazanavir generic – Laurus Labs</td>
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<tr>
<td>23.</td>
<td>Emtricitabine (EMTRIVA®, FTC) – Gilead</td>
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<td>Emtricitabine generic – Cipla</td>
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<td>Tenofovir disoproxil fumarate+emtricitabine (TRUVADA®, TDF) – Gilead</td>
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<td>24.1</td>
<td>Tenofovir disoproxil fumarate+emtricitabine generic – Mylan</td>
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<td>Abacavir+lamivudine (EPZICOM®, KIVEXA®, EPZ) – Viiv</td>
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<tr>
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<td>Abacavir+lamivudine generic – Teva</td>
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<td>Abacavir+lamivudine generic – Dr. Reddys (no longer partic.)</td>
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<td>Abacavir+lamivudine generic – Aurobindo (no longer partic.)</td>
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<td>Abacavir+lamivudine generic – Cipla</td>
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<td>Abacavir+lamivudine generic – Lupin</td>
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<td>Abacavir+lamivudine generic – Apotex</td>
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<td>Tenofovir disoproxil fumarate+emtricitabine maleate+emtricitabine generic – Aurobindo</td>
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<tr>
<td>26.1</td>
<td>Tenofovir disoproxil fumarate+emtricitabine generic – Apotex</td>
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</tr>
<tr>
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<tr>
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<tr>
<td>27.</td>
<td>Entecavir (BARAACLE®, ETV) – BMS</td>
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<tr>
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<td>Entecavir generic – Teva</td>
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