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 people
        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 Was a Dating Ultrasound performed: Indicate if a dating ultrasound was performed on the patient.
      • If no, move to Subsection 1.4
      • If yes, provide the date of the ultrasound and the Corrected Estimated Date of Delivery (CEDD) from the test.
   1.4 Patient Age: Provide age of the pregnant person at time of conception.
   1.5 Race: Check the appropriate box for the pregnant person’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, check the prenatal test performed and provide the date in DD/MMM/YYYY format, or the gestational
        age. If “Other (specify)” is selected list the name of the prenatal test (i.e., Ultrasound, Amniocentesis, MSAFP).
   2.2 Evidence of a Structural Defect or genetic abnormality: Indicate if a structural defect(s) and/or a genetic
      abnormality 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 [link to CDC definition].
        • 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
**ANTIRETROVIRAL PREGNANCY REGISTRY**

**REGISTRATION FORM**

**FOR OFFICE USE ONLY**

- Registry Patient ID __________
- HCP ID __________

- Prospective ☐
- Retrospective ☐
- 100% Provider ☐

- Registry date of notification ______  _____  _____

- Phone ☐

**Country of report origin_________ State (U.S. only)_________**

**Date patient first seen during this pregnancy or Sponsor date of notification of pregnancy**

<table>
<thead>
<tr>
<th>Date:</th>
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</table>

**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:

**Was the clinical study conducted in pregnant women?**

- Yes ☐
- No ☐
- Unknown ☐

1.2 Last Menstrual Period ______  _____  _____

<table>
<thead>
<tr>
<th>Date:</th>
<th>DD</th>
<th>MMM</th>
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</thead>
</table>

1.3 Corrected EDD ______  _____  _____

<table>
<thead>
<tr>
<th>Date:</th>
<th>DD</th>
<th>MMM</th>
<th>YYYY</th>
</tr>
</thead>
</table>

1.4 Patient Age: _______ (at conception)

1.5 Race: ☐ White ☐ Black ☐ Hispanic ☐ Asian

| Race: | ☐ White | ☐ Black | ☐ Hispanic | ☐ Asian |

1.6 Maternal Information (specify): __________________________________

**2. PRENATAL TESTS**

2.1 Was a prenatal test done?

- No (go to section 3) ☐
- Yes (complete below and question 2.2) ☐

<table>
<thead>
<tr>
<th>Date:</th>
<th>DD</th>
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</table>

2.2 Is there evidence of a structural defect from one or more of these prenatal tests?

| Defect: | Yes ☐ | No ☐ | Unknown ☐ |

2.3 Test(s) done:

- Ultrasound ______  _____  _____
- Amniocentesis ______  _____  _____
- Cystic Fibrosis Mutation Analysis ______  _____  _____
- Fetal Echo ______  _____  _____
- First Trimester Screen ______  _____  _____
- MSAFP/serum markers ______  _____  _____
- Nuchal Translucency ______  _____  _____
- Other (specify): ______  _____  _____

| Category: | Yes ☐ | No ☐ | Unknown ☐ |

**3. CLINICAL INDICATORS**

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 ☐

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

| Category: | Yes ☐ | No ☐ | Unknown ☐ |

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 ☐

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

**HEALTH CARE PROVIDER INFORMATION**

<table>
<thead>
<tr>
<th>Name:</th>
<th>Specialty:</th>
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<th>Address:</th>
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<th>Alternate Contact:</th>
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<tr>
<th>Provider's Signature:</th>
<th>Date:</th>
<th>DD</th>
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</thead>
</table>

**Contact:**

Fax: 800-800-1052 (US, Canada toll-free)

+1-910-256-0837 (International)

Email: SM_APR@APRegistry.com
### 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 (1-61)</th>
<th>Total Daily Dose</th>
<th>Route</th>
<th>Pt Taking Med. Prior to Conception?</th>
<th>Date Treatment Course Began (DD-MM-YYYY)</th>
<th>Date Treatment Stopped (DD-MM-YYYY), Gestational Age Course Began (0 weeks = prior to conception)</th>
<th>Ongoing following delivery?</th>
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<tbody>
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<td>1 = Oral</td>
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<td>2 = IV</td>
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<td>3 = SubQ/IM</td>
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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.

1. Abacavir (ZIAGEN®, ABC) – ViV
   1.1 Abacavir generic – Hetero
   1.2 Abacavir generic – Apotex
   1.3 Abacavir generic – Mylan
   1.4 Abacavir generic – Strides
   1.5 Abacavir generic – Aurobindo (no longer partic.)
   1.6 Abacavir generic – Cipla
   1.99 Abacavir generic (unknown manufacturer)

2. Didanosine (VIDEX®, VIDEX® EC, ddI) – BMS
   2.1 Didanosine generic – Teva
   2.2 Didanosine generic – Aurobindo (no longer manuf.)
   2.3 Didanosine generic – Mylan (no longer manuf.)
   2.99 Didanosine (unknown manufacturer)

3. Efavirenz (SUSTIVA®/EPV) – BMS
   3.1 Efavirenz (STOCIRAN®/EPV) – Merck
   3.2 Efavirenz generic – Hetero
   3.3 Efavirenz generic – Aurobindo (no longer partic.)
   3.4 Efavirenz generic – Mylan (no longer manuf.)
   3.5 Efavirenz generic – Strides
   3.6 Efavirenz generic – Cipla
   3.99 Efavirenz (unknown manufacturer)

4. Lamivudine (EPIVIR®, ZEFIX®, 3TC, HEPITEC, HEPTODIN, HEPTOVIR) – ViV
   4.1 Lamivudine generic – Hetero
   4.2 Lamivudine + tenofovir disoproxil fumarate generic – Hetero (no longer manuf.)
   4.3 Lamivudine generic – Apotex
   4.4 Lamivudine generic – Aurobindo (no longer partic.)
   4.5 Lamivudine generic – Lannett (no longer manuf.)
   4.6 Lamivudine generic – Lupin
   4.7 Lamivudine generic – Mylan (no longer manuf.)
   4.8 Lamivudine generic – Cipla
   4.9 Lamivudine generic – Strides
   4.10 Lamivudine generic – Macleods
   4.99 Lamivudine (unknown manufacturer)

5. Lamivudine+zidovudine (COMBIVIR®, CBV) – ViV
   5.1 Lamivudine+zidovudine generic – Hetero
   5.2 Lamivudine+zidovudine generic – Teva
   5.3 Lamivudine+zidovudine generic – Aurobindo (no longer partic.)
   5.4 Lamivudine+zidovudine generic – Lupin
   5.5 Lamivudine+zidovudine generic – Strides
   5.6 Lamivudine+zidovudine generic – Mylan (no longer manuf.)
   5.7 Lamivudine+zidovudine generic – Macleods
   5.8 Lamivudine+zidovudine generic – Cipla
   5.9 Lamivudine+zidovudine generic – Apotex
   5.99 Lamivudine+zidovudine generic (unknown manufacturer)

6. Nelfinavir (VIRACEPT®, NFV) – ViV/Pfizer

7. Nevirapine (VIRAMUNE®, VIRAMUNE® XR™, NVP) – BI
   7.1 Nevirapine generic – Hetero
   7.2 Nevirapine generic – Prinston (no longer partic.)
   7.3 Nevirapine/nevirapine ER generic – Sciegen (no longer manuf.)
   7.4 Nevirapine/nevirapine ER generic – Aurobindo (no longer manuf.)
   7.5 Nevirapine/nevirapine ER generic – Mylan (no longer manuf.)
   7.6 Nevirapine generic – Strides
   7.7 Nevirapine ER generic – Sandoz (no longer partic.)
   7.8 Nevirapine/nevirapine ER generic – Cipla
   7.9 Nevirapine ER generic – Alogen
   7.10 Nevirapine ER generic – Teva
   7.11 Nevirapine/nevirapine ER generic – Mylan
   7.12 Nevirapine/Nevirapine ER generic – Macleods
   7.99 Nevirapine (unknown manufacturer)

8. Ritonavir (NORVIR®, RTV) – AbbVie
   8.1 Ritonavir generic – Hilma
   8.2 Ritonavir generic – Amneal
   8.3 Ritonavir generic – Aurobindo (no longer partic.)
   8.4 Ritonavir generic – Hetero
   8.99 Ritonavir (unknown manufacturer)

9. Saquinavir (FORTOVASE®, SQV-SGC) – Roche (no longer manuf./no longer partic.)
   9.1 Saquinavir generic – Hetero
   9.99 Saquinavir (unknown manufacturer)

10. Saquinavir mesylate (INVIRASE®, SQV-HGC) – Roche (no longer partic.)
   11. Stavudine (ZERIT®, d4T) – BMS
   11.1 Stavudine generic – Mylan (no longer manuf.)
   11.2 Stavudine generic – Aurobindo (no longer manuf.)
   11.3 Stavudine generic – Cipla
   11.4 Stavudine generic – Hetero
   11.99 Stavudine generic (unknown manufacturer)

12. Zalcitabine (HIVID®, ddc) – Roche (no longer manuf./no longer partic.)

13. Zidovudine (RETROVIR®, ZDV) – ViV
   13.1 Zidovudine oral generic – Ranbaxy (no longer manuf.)
   13.2 Zidovudine oral generic – ViV
   13.3 Zidovudine oral generic – Hikma
   13.4 Zidovudine oral generic – Aurobindo (no longer partic.)
   13.5 Zidovudine oral generic – Cipla
   13.6 Zidovudine oral generic – Mylan (no longer manuf.)
   13.7 Zidovudine oral generic – Hetero
   13.8 Zidovudine oral generic – Sunshine Lakes (no longer manuf.)
   13.9 Zidovudine oral generic – Ipsa (no longer manuf.)
   13.10 Zidovudine oral generic – Apotex
   13.99 Zidovudine oral (unknown manufacturer)

14. Amprenavir (AGENESASE®, APV) – ViV (no longer manuf.)

15. Indinavir (CRIXIVAN®, IDV) – Merck
   15.1 Indinavir generic – Hetero
   15.99 Indinavir (unknown manufacturer)

16. Delavirdine mesylate (RESPICORT®, DLV) – ViV (no longer manuf.)

17. Lopinavir+ritonavir (KALETRA®, ALUVIA®, LPV/r) – Abbvie
   17.1 Lopinavir+ritonavir generic – Lannett
   17.2 Lopinavir+ritonavir generic – Laurus Labs
   17.3 Lopinavir+ritonavir generic – Hetero
   17.99 Lopinavir+ritonavir (unknown manufacturer)

18. Abacavir+lamivudine+zidovudine (TRIZIVIR®, TZV) – ViV
   18.1 Abacavir+lamivudine+zidovudine generic – Lupin
   18.2 Abacavir+lamivudine+zidovudine generic – Apotex
   18.3 Abacavir+lamivudine/zidovudine generic – Hetero
   18.99 Abacavir+lamivudine/zidovudine (unknown manufacturer)

19. Tenofovir disoproxil fumarate (VIREAD®, TDF) – Gilead
   19.1 Tenofovir disoproxil fumarate generic – Hetero
   19.2 Tenofovir disoproxil fumarate generic – Apotex
   19.3 Tenofovir disoproxil maleate generic – Mylan
   19.4 Tenofovir disoproxil fumarate generic – Strides
   19.5 Tenofovir disoproxil succinate generic – Dr. Reddys (no longer partic.)
   19.6 Tenofovir disoproxil fumarate generic – Aurobindo (no longer partic.)
   19.7 Tenofovir disoproxil fumarate generic – Macleods
   19.8 Tenofovir disoproxil fumarate generic – Strides
   19.9 Tenofovir disoproxil fumarate generic – Zentiva (no longer partic.)
   19.10 Tenofovir disoproxil fumarate generic – Gali
   19.11 Tenofovir disoproxil fumarate generic – Laurus Labs (no longer manuf.)
   19.12 Tenofovir disoproxil fumarate generic – Mylan
   19.13 Tenofovir disoproxil fumarate generic – Cipla
   19.14 Tenofovir disoproxil fumarate generic – Pharmascience
   19.99 Tenofovir disoproxil fumarate (unknown manufacturer)

20. Adefovir dipivoxil (HEPSERA®, ADV) – Gilead
   20.1 Adefovir dipivoxil generic – SigmaPharm
   20.2 Adefovir dipivoxil generic – Apotex
   20.99 Adefovir dipivoxil (unknown manufacturer)

21. Enfuvirtide (FUZEON®, T-20) – Roche (no longer partic.)

22. Atazanavir (REYATAZ®, ATV) – BMS
   22.1 Atazanavir generic – Aurobindo (no longer partic.)
   22.2 Atazanavir generic – Cipla
   22.3 Atazanavir generic – AnNeal
   22.4 Atazanavir generic – Laurus Labs
   22.5 Atazanavir generic – Hetero
   22.99 Atazanavir (unknown manufacturer)

23. Emtricitabine (EMTRIVA®, FTC) – Gilead
   23.1 Emtricitabine generic – Cipla
   23.2 Emtricitabine generic – Mylan
   23.99 Emtricitabine (unknown manufacturer)

24. Fosamprenavir calcium (LEXIVA®, FOS) – ViV
   24.1 Fosamprenavir calcium generic – Mylan
   24.99 Fosamprenavir calcium (unknown manufacturer)
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<th>Drug Name</th>
<th>Manufacturer/Trade Name</th>
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