

# ANTIRETROVIRAL PREGNANCY REGISTRY REGISTRATION FORM

Fax to: 800-800-1052 (US, Canada)  
+910-256-0637 (International) or +32-2-714-5024 (Europe)  
00800-5812-1658 (UK, Germany, France)  
888-259-5618 (Brazil)

FOR OFFICE USE ONLY

(1)

Registry Patient ID \_\_\_\_\_ HCP ID \_\_\_\_\_  
Prospective  Retrospective  100% provider   
Country \_\_\_\_\_ State \_\_\_\_\_  
Report type Original U/L  MP  Current U/L  MP   
Registry date of notification \_\_\_\_\_  Phone

|  |   |  |
|--|---|--|
| <b>Patient (Log) ID:</b> _____<br><i>Note: To help assure patient anonymity the Registry uses a Registry assigned patient ID to refer to your patient to obtain follow-up and outcome information.</i> | <b>Registry assigned ID number or Sponsor MCN</b> _____ | <b>Date patient first seen during this pregnancy</b><br>Date: _____<br>M      D      Y |
|--|---|--|

**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 trial conducted in pregnant women?  Yes  No  Unknown

1.2 Last Menstrual Period \_\_\_\_\_  
 M      D      Y

1.3 Corrected EDD \_\_\_\_\_ (e.g., by ultrasound)  
 M      D      Y

1.4 Patient Age: \_\_\_\_\_ (at conception)

1.5 Race:  White  Black  
 Hispanic  Asian  
 Other (specify) \_\_\_\_\_

|  |  |
|--|--|
| <p><b>2. PRENATAL TESTS</b></p> <p>2.1 Was a prenatal test done?<br/> <input type="checkbox"/> No (go to section 3)<br/> <input type="checkbox"/> Yes (complete below and question 2.2)<br/>                 Date when test(s) done: _____</p> <p>(✓) test(s) <input type="checkbox"/> Ultrasound _____ date<br/> <input type="checkbox"/> Ultrasound _____ date<br/> <input type="checkbox"/> Ultrasound _____ date<br/> <input type="checkbox"/> Amniocentesis _____ date<br/> <input type="checkbox"/> MSAFP/serum markers _____ date<br/> <input type="checkbox"/> Other: _____ date<br/> <input type="checkbox"/> Unknown (go to section 3)</p> | <p>2.2 Is there evidence of a <u>structural</u> defect from one or more of these prenatal tests?<br/> <input type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> Unknown. If yes, Specify defect _____<br/> <input type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> Unknown. If yes, Specify defect _____<br/> <input type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> Unknown. If yes, Specify defect _____<br/> <input type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> Unknown. If yes, Specify defect _____<br/> <input type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> Unknown. If yes, Specify defect _____<br/> <input type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> Unknown. If yes, Specify defect _____</p> |
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**3. CLINICAL INDICATORS (at the START of pregnancy)**

3.1 Clinical Categories (✓ all that apply at the **start** of pregnancy):

A. Asymptomatic, acute (primary) HIV or PGL\*  
 B. Symptomatic, not (A) or (C) conditions  
 C. Other AIDS-indicator conditions and/or CD4<200  
 D. HIV prophylaxis  
 E. Hepatitis B (HBV)  
 F. Hepatitis C (HCV)

3.2 CD4+ T-cell Categories (at **start** of pregnancy)  
 ≥ 500 µL  
 200-499 µL  
 <200 µL  
 Not applicable

3.3 Hepatitis Severity Indicator (at **start** of pregnancy):  
 A. Compensated liver disease (Pugh score <7)  
 B. Decompensated liver disease (Pugh score ≥7)  
 C. Not applicable

\*PGL-persistent generalized lymphadenopathy  
 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 _____                 | Specialty _____               |
| Address _____              | Phone _____                   |
| _____                      | Fax _____                     |
| Alternate Contact _____    | Email _____                   |
| Provider's Signature _____ | Date _____<br>M      D      Y |

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# ANTIRETROVIRAL PREGNANCY REGISTRY ANTIVIRAL THERAPY DURING PREGNANCY

*(Initiated at registration and completed at follow-up)*

FOR OFFICE USE ONLY

(2)

Registry ID \_\_\_\_\_

Update

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

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.

## 4. ANTIVIRAL THERAPY DURING PREGNANCY

1. Use the med. codes below for antiviral medication taken during pregnancy. If not coded, **Specify Medication**.

- |  |  |
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| <ul style="list-style-type: none"> <li>1. Abacavir (ZIAGEN<sup>®</sup>, ABC)</li> <li>2. Didanosine (VIDEX<sup>®</sup>, VIDEX<sup>®</sup> EC, ddl)</li> <li>2.1 Didanosine generic – Teva Pharmaceuticals</li> <li>2.2 Didanosine generic – Aurobindo</li> <li>2.3 Didanosine generic - Mylan</li> <li>2.99 Didanosine (unknown manufacturer)</li> <li>3. Efavirenz (SUSTIVA<sup>®</sup>, EFV)</li> <li>3.1 Efavirenz (STOCRIN<sup>®</sup>, EFV)</li> <li>3.2 Efavirenz generic - Hetero</li> <li>3.99 Efavirenz (unknown manufacturer)</li> <li>4. Lamivudine (EPIVIR<sup>®</sup>, 3TC)</li> <li>4.1 Lamivudine generic - Hetero</li> <li>4.2 Lamivudine+tenofovir df generic - Hetero</li> <li>4.99 Lamivudine (unknown manufacturer)</li> <li>5. Lamivudine+zidovudine (COMBIVIR<sup>®</sup>, ZDV+3TC)</li> <li>5.1 Lamivudine+zidovudine generic - Hetero</li> <li>5.99 Lamivudine+zidovudine (unknown manufacturer)</li> <li>6. Nelfinavir (VIRACEPT<sup>®</sup>, NFV)</li> <li>7. Nevirapine (VIRAMUNE<sup>®</sup>, NVP)</li> <li>7.1 Nevirapine generic - Hetero</li> <li>7.99 Nevirapine (unknown manufacturer)</li> <li>8. Ritonavir (NORVIR<sup>®</sup>, RTV)</li> <li>9. Saquinavir (FORTOVASE<sup>®</sup>, SQV-SGC)</li> <li>10. Saquinavir mesylate (INVIRASE<sup>®</sup>, SQV-HGC)</li> <li>11. Stavudine (ZERIT<sup>®</sup>, d4T)</li> <li>11.1 Stavudine generic – Mylan</li> <li>11.2 Stavudine generic – Aurobindo</li> <li>11.3 Stavudine generic – Cipla</li> <li>11.4 Stavudine generic - Hetero</li> <li>11.99 Stavudine generic – unknown manufacturer</li> <li>12. Zalcitabine (HIVID<sup>®</sup>, ddC)</li> <li>13. Zidovudine (RETROVIR<sup>®</sup>, ZDV)</li> </ul> | <ul style="list-style-type: none"> <li>13.1 Zidovudine generic - Ranbaxy</li> <li>13.2 Zidovudine generic – Teva/GSK</li> <li>13.3 Zidovudine generic – Roxane/BI</li> <li>13.4 Zidovudine generic – Aurobindo</li> <li>13.5 Zidovudine generic – Cipla</li> <li>13.6 Zidovudine generic – Mylan</li> <li>13.7 Zidovudine generic – Hetero</li> <li>13.99 Zidovudine (unknown manufacturer)</li> <li>14. Amprenavir (AGENERASE<sup>®</sup>, APV)</li> <li>15. Indinavir (CRIXIVAN<sup>®</sup>, IDV)</li> <li>16. Delavirdine mesylate (RESCRIPTOR<sup>®</sup>, DLV)</li> <li>17. Lopinavir+ritonavir (KALETRA<sup>®</sup>, ALUVIA<sup>®</sup>, LPV/r)</li> <li>18. Abacavir+lamivudine+zidovudine (TRIZIVIR<sup>®</sup>, TZV)</li> <li>19. Tenofovir disoproxil fumarate (VIREAD<sup>®</sup>, TDF)</li> <li>19.1 Tenofovir disoproxil fumarate generic - Hetero</li> <li>20. Adefovir dipivoxil (HEPSERA<sup>®</sup>, ADV)</li> <li>21. Enfuvirtide (FUZEON<sup>®</sup>, T-20)</li> <li>22. Atazanavir sulfate (REYATAZ<sup>®</sup>, ATV)</li> <li>23. Emtricitabine (EMTRIVA<sup>®</sup>, FTC)</li> <li>24. Fosamprenavir calcium (LEXIVA<sup>®</sup>, FOS)</li> <li>25. Abacavir+lamivudine (EPZICOM<sup>®</sup>, EPZ)</li> <li>26. Tenofovir disoproxil fumarate+emtricitabine (TRUVADA<sup>®</sup>, TVD)</li> <li>27. Entecavir (BARACLUDE<sup>®</sup>, ETV)</li> <li>28. Tipranavir (APTIVUS<sup>®</sup>, TPV)</li> <li>29. Efavirenz+tenofovir disoproxil fumarate+emtricitabine (ATRIPLA<sup>™</sup>, ATR)</li> <li>30. Telbivudine (TYZEKA<sup>®</sup>, SEBIVO<sup>®</sup>, LdT)</li> <li>31. Darunavir (PREZISTA<sup>™</sup>, DRV)</li> <li>32. Raltegravir (ISENTRESS<sup>™</sup>, RAL)</li> <li>33. Maraviroc (SELZENTRY<sup>™</sup>, CELSENTRI<sup>™</sup>, MVC)</li> <li>34. Etravirine (INTELENCE<sup>™</sup>, ETR)</li> </ul> |
|--|--|

2. In the following table, describe each course or change in route for each applicable therapy.

| Med. Code (1-34)<br>or<br>if no code indicated, please<br>write medication name and<br>indicate if generic | Total Daily Dose<br>(mg/day or<br>mg/kg/hr) | Route<br>(enter code)<br>1 = oral<br>2 = IV<br>3 = sub-Q | Pt Taking Med.<br>at<br>Conception?<br>1 = Yes<br>2 = No<br>3 = Unknown | Date Treatment Course Began (M/D/Y)<br><b>OR</b><br>Gestational Age Course Began<br>(0 weeks = prior to conception)<br>If gestational age, calculation source:<br><input type="checkbox"/> (LMP)<br><input type="checkbox"/> (corrected EDD) | Date Treatment Stopped (M/D/Y)<br><b>OR</b><br>Ongoing?<br>(Note: Ongoing = ongoing<br>Following delivery) |
|--|---|--|---|--|--|
| Course   |   |  |   |  |  |
|  |   |  |   |  | or <input type="checkbox"/> ongoing  |
|  |   |  |   |  | or <input type="checkbox"/> ongoing  |
|  |   |  |   |  | or <input type="checkbox"/> ongoing  |
|  |   |  |   |  | or <input type="checkbox"/> ongoing  |
|  |   |  |   |  | or <input type="checkbox"/> ongoing  |
|  |   |  |   |  | or <input type="checkbox"/> ongoing  |

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