

**RYAN WHITE PROGRAM  
LETTER OF MEDICAL NECESSITY FOR  
ANTIRETROVIRAL PHENOTYPE RESISTANCE ASSAYS FOR EXPERIENCED PATIENTS  
COVERAGE IS LIMITED TO A MAXIMUM OF ONE PHENOTYPE IN ANY CONSECUTIVE 12-MONTH PERIOD.  
(*NOT REQUIRED FOR VIRTUAL PHENOTYPE TESTS*)**

Date: \_\_\_\_\_

As the primary medical caretaker for \_\_\_\_\_ it is my considered opinion that he/she requires HIV phenotypic resistance testing. The following criteria have been met:

1. The patient at any time in the past has failed two (2) or more antiretroviral (ARV) regimens;
2. Results of at least one, preferably more, prior genotype(s) must be available in the chart and Resistance to two or more drugs per class in at least two classes of ARVs is present on prior genotype(s);

**AND ONE OF THE FOLLOWING (check-off the appropriate condition below):**

\_\_\_ Prior genotype(s) show(s) resistance to at least 2 PIs other than ritonavir and use of a PI is being considered;

**OR**

\_\_\_ Lopinavir/ritonavir is being considered in a PI-experienced patient with four or more mutations associated with resistance to lopinavir/ritonavir on a prior genotype;

**OR**

\_\_\_ Four or more mutations at codons associated with PI cross-resistance are present;

**OR**

\_\_\_ M184V mutation is present in the presence of 3 or more NRTI-associated mutations (NAMs);

**OR**

\_\_\_ K65R mutation is present, or other mutations associated with NRTI cross-resistance (69 insertion complex or 151 complex);

**OR**

\_\_\_ Rescue ARV regimens guided by results of two or more prior genotypes have failed to suppress viral replication, whether mutations present or not, and the patient has been determined to be adherent on re-evaluation. (Requires a minimum of two prior genotypes.)

I understand HIV phenotypic resistance testing for experienced patients may only be ordered under the following conditions:

1. The above criteria have been met and are fully documented in the patient's medical record;
2. Adherence has been discussed with the patient on an on-going basis as part of his/her medical treatment, and it has been determined that the patient is fully adherent with his/her current ART regimen;
3. The patient's plasma HIV RNA (viral load) at the time of testing must be at least 1000 co/ml within the past month (attach copy to letter of medical necessity);
4. The patient must be on antiretroviral medications at the time of testing.

Sincerely,

\_\_\_\_\_, M.D.

\_\_\_\_\_  
Print Physician's name

\_\_\_\_\_  
Florida Medical License # (ME#)

\_\_\_\_\_  
Patient's 10 digit Medicaid # (if applicable)

\_\_\_\_\_  
Patient's CIS # (assigned by the Ryan White Program Service Delivery Information System)

**Please note:** All questions should be directed to the Office of Management and Budget-Grants Coordination/Ryan White Program, at (305) 375-4742. Requests for information/clarification of a clinical nature will be forwarded by Miami-Dade County to the Miami-Dade HIV/AIDS Partnership Medical Care Subcommittee and/or a qualified member of the Subcommittee (physician, nurse, registered dietitian, etc.). Pursuant to the most current Professional Service Agreement for Ryan White Program-funded services, the service provider must make available to Miami-Dade County access to all client charts (including electronic files), service utilization data, and medical records pertaining to this Agreement during on-site verification or audit by County personnel and/or authorized individuals to confirm the accuracy of all information reported by the service provider.

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