***Notation: RYAN WHITE PROGRAM PRESCRIPTION DRUG FORMULARY COMMENTS**

**Updates Effective 11/10/2014 (unless otherwise noted)**

**ATTACHMENT A**

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| **A** | *These medications may be covered by the Ryan White Part A/Minority AIDS Initiative (MAI) Programs when the medications are not available through the State of Florida's AIDS Drug Assistance Program (ADAP).* |
| **B** | *In order for a client to obtain this medication through the Part A or MAI Programs, one of the two conditions (histoplasmosis or aspergillosis) must have been identified and documented in the client's chart by his/her physician. Part A or MAI funds may only be used to cover one of the two conditions. In addition, the **Ryan White Program Letter of Medical Necessity for Sporanox** is required. This Letter of Medical Necessity must be submitted to the appropriate Ryan White Program pharmacy based on Average Wholesale Pricing (AWP)/Public Health Services 340B (PHS) limitations.* |
| **C** | *Notation no longer applicable.* |
| **D** | *These nutritional supplements are available in powder form only and require a Letter of Medical Necessity from both a Physician and a Nutritionist. This Letter of Medical Necessity must be submitted to the appropriate Ryan White Program pharmacy based on Average Wholesale Pricing (AWP)/Public Health Services 340B (PHS) limitations.* |
| **E** | *Notation no longer applicable.* |
| **F** | *Part A or MAI funds may only be used to reimburse for this medication for treatment of Toxoplasmosis; this diagnosis must be written on the prescription.* |
| **G** | *Notation no longer applicable.* |
| **H** | *The Ryan White Program Letter of Medical Necessity for Testosterone is required and must be submitted to the appropriate Ryan White Program pharmacy based on Average Wholesale Pricing (AWP)/Public Health Services 340B (PHS) limitations.* |
| **I** | *Notation no longer applicable.* |
| **J** | *Part A or MAI funds may only be used to reimburse for these medications for the treatment of indications experienced by HIV+ children 12 years and under. These medications are only available in liquid or suspension form.* |

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**Updates Effective 11/10/2014 (unless otherwise noted)**

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| **K** | *Notation no longer applicable.* |
| **L** | *In order to receive Eprosartan (Teveten) through the Ryan White Part A or MAI Programs, the patient must have had a prior history of intolerability to the use of Angiotensin Converting Enzyme (ACE) Inhibitors.* |
| **M** | *Notation no longer applicable.* |
| **N** | *Notation no longer applicable.* |
| **O** | *Notation no longer applicable.* |
| **P** | *Ofloxacin (Ocuflox) is restricted to ophthalmic/ophthalmologist use only.* |
| **Q** | *Physicians prescribing Neupogen to patients needing to access Part A or MAI pharmaceutical services are required to complete a Ryan White Program Letter of Medical Necessity for Neupogen (Filgrastim). Prescribing physicians* **must** *submit the Ryan White Program Letter of Medical Necessity to the appropriate Ryan White Program pharmacy based on Average Wholesale Pricing (AWP)/Public Health Services 340B (PHS) limitations along with the* **original** *prescription and* **lab** *results dated within the last two (2) months.* |
| **R** | *Physicians prescribing Procrit or Epogen to patients needing to access Part A or MAI pharmaceutical services are required to complete a Ryan White Program Letter of Medical Necessity for Procrit or Epogen (Epoetin Alpha). Prescribing physicians* **must** *submit the Ryan White Program Letter of Medical Necessity to the appropriate Ryan White Program pharmacy based on Average Wholesale Pricing (AWP)/Public Health Services 340B (PHS) limitations along with the* **original** *prescription and* **lab** *results dated within the last two (2) months.* |
| **S** | *There is no generic equivalent for this brand name product.* |
| **T** | *This drug is not indicated as a sleep aid and should only be used to treat bipolar disorders and schizophrenia.* |

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**Updates Effective 11/10/2014 (unless otherwise noted)**

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| **U** | *The **Ryan White Program Letter of Medical Necessity for Enfuvirtide (Fuzeon)** is required. This Letter of Medical Necessity must be submitted to appropriate Ryan White Program pharmacy based on Average Wholesale Pricing (AWP)/Public Health Services 340B (PHS) limitations. The primary medical provider must certify it is medically necessary to add Enfuvirtide (Fuzeon) to this patient's antiretroviral regimen. The patient has been on Enfuvirtide (Fuzeon) through another funding source but this funding source is no longer available. This condition necessitates Ryan White Part A or MAI coverage for continuity of care. In addition, the patient must meet one (1) of the following appropriate criteria below:*<br><br>*1. The patient is eligible for the AIDS Drug Assistance Program (ADAP) and there is a completed application pending approval. A new prescription is allowed for a maximum of **60 days** and no refill authorizations are accepted;*<br><br>**OR**<br><br>*2. The patient is not eligible for ADAP and must be covered under Ryan White Part A or MAI pending another payment source. A new prescription is allowed for a maximum of **90 days** and no refill authorizations are accepted.* |
| **V** | *The **Ryan White Program Letter of Medical Necessity for Tipranavir (Aptivus)** is required. This Letter of Medical Necessity must be submitted to the appropriate Ryan White Program pharmacy based on Average Wholesale Pricing (AWP)/Public Health Services 340B (PHS) limitations. As the prescribing healthcare provider, it is his/her considered opinion that Tipranavir (Aptivus) is medically necessary for the patient and should be added to his/her antiretroviral regimen. In addition, the prescribing healthcare provider must certify that the following criteria have been met:*<br><br>*1. The patient has failed treatment with Lopinavir/ritonavir (Kaletra) and all three classes of antiretrovirals;*<br>**AND**<br>*2. The healthcare provider has fully discussed all issues and consequences related to non-adherence with the patient.* |

***Notation: RYAN WHITE PROGRAM PRESCRIPTION DRUG FORMULARY COMMENTS**

**Updates Effective 11/10/2014 (unless otherwise noted)**

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| **W** | *Before prescribing Selzentry (Maraviroc) to any client**, and only if ViiV Healthcare is no longer covering the cost of the assays through its Tropism Assistance Program (TAP)**, physicians and other prescribing clinicians must complete a Ryan White Program Letter of Medical Necessity for a Highly Sensitive Tropism Assay (Trofile, Trofile DNA, or Quest Diagnostics Tropism assay). Providers must adhere to the Sample Collection and Handling Requirements for the Trofile, Trofile DNA, and Quest Diagnostics Tropism assays.* |
| **X** | *The Florida Department of Health issued an Interoffice Memorandum, dated January 31, 2008, with information regarding Intelence (Etravirine). Accompanying this Memorandum was a document titled "Intelence (Etravirine) Tablets – Full Prescribing Information." This information comes from the manufacturer. It is extremely important for providers and clients to understand the prescribing information related to Intelence (Etravirine).* |
| **Y** | *The **Ryan White Program Letter of Medical Necessity for Roxicodone (Oxycodone) and Percocet (Oxycodone/APAP)** is required. This Letter of Medical Necessity must be submitted to the appropriate Ryan White Program pharmacy based on Average Wholesale Pricing (AWP)/Public Health Services 340B (PHS) limitations. In addition, physicians prescribing these pain medications must adhere to the related legislation found in Florida Administrative Code 64B8-9.013, Standards for the Use of Controlled Substances for the Treatment of Pain, and Florida Statutes 458.309 and 458.331.* |
| **Z** | *Lantus, Levemir, Humalog and Novolog are restricted to dispensing in vial form only. Miami-Dade County Office of Grants Coordination staff is authorized to make an exception to this restriction subject to consulting with the medical provider.* |
| **AA** | *Strattera (Atomoxetine) is restricted to prescribing by a psychiatrist for patients with a diagnosis of attention-deficit hyperactivity disorder (ADHD) and a history of substance abuse only.* |
| **BB** | *This medication was added to the Ryan White Program Prescription Drug Formulary as a cost saving measure to prevent costly complications for anorectal surgery patients. This medication is restricted to anorectal surgery patients with a maximum utilization of a 30-day supply. This medication is also limited to generic only.* |
| **CC** | *Notation no longer applicable.* |
| **DD** | *This medication is limited to treatment for Mycobacterium avium-intracellulare (MAI), Mycobacterium avium complex (MAC), and Pneumocystis carinii pneumonia (PCP) only.* |

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**Updates Effective 11/10/2014 (unless otherwise noted)**

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| **EE** | *Ranitidine must be used (now allowable in 75mg, 150mg, and 300mg dosages) for at least one month prior to filling a prescription for Omeprazole, unless the client has failed on Ranitidine or if complications require the use of Omeprazole only. Documentation in the client chart must support the failure of Ranitidine in the client's case.* |
| **FF** | *Prenatal vitamins are restricted to pregnant women only.* |
| **GG** | *Vitamin B6 is restricted to clients who are taking Isoniazid (INH).* |
| **HH** | *The following vitamins may be dispensed as a 90-day supply: Prenatal, B-6, B-12, and multivitamins. Prescribing practitioners and pharmacies are strongly encouraged to write and fill prescriptions, respectively, for these vitamins as a 90-day supply, where appropriate to the client's treatment plan. This is a cost saving measure that will yield significant savings to the program since one monthly dispensing fee would be incurred for a 90-day supply rather than three monthly dispensing fees for three individual 30-day supplies of vitamins.* |
| **II** | *The Florida Department of Health issued an Interoffice Memorandum, dated July 18, 2011, with information regarding the approval by the U.S. Food and Drug Administration (FDA) of Edurant (Rilpivirine), a new NNRTI for the treatment of HIV in antiretroviral (ARV) naïve patients.* |
| **JJ** | *The Partnership reviewed and/or approved a request by the Oral Health Care Subcommittee to recommend adding two fluoride products, both PreviDent Brush-on Gel and PreviDent 5000 Dry Mouth toothpaste to the Ryan White Program Prescription Drug Formulary. These dental medications are cost effective in that they prevent tooth decay that would cause more costly dental procedures.* |
| **KK** | *The Florida Department of Health issued an Interoffice Memorandum, dated November 17, 2011, with information regarding the approval by the U.S. Food and Drug Administration (FDA) of Complera (Emtricitabine/Rilpivirine/Tenofovir DF), a complete regimen for the treatment of HIV infection in antiretroviral (ARV) naïve patients because it contains a Nonnucleoside Reverse Transcriptase Inhibitor [i.e., Edurant (Rilpivirine)] and two Nucleoside Reverse Transcriptase Inhibitors [i.e., Truvada (Emtricitabine and Tenofovir DF)].* |

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| **LL** | *A Selzentry (maraviroc) prescription must be accompanied by a copy of the Highly Sensitive Tropism Assay (test) that is CCR5-tropic on the initial prescription. Any patient (client) entering the Ryan White Program already on Selzentry (maraviroc) is exempt from this requirement, but will need to have the previous usage clearly documented on the prescription* |
| **MM** | *These mesalamine products, both Rowasa (mesalamine enema) and Canasa (mesalamine suppository), were added to the Ryan White Program Prescription Drug Formulary as a cost saving measure with the restriction that mesalamine must be prescribed by a colorectal surgeon.* |
| **NN** | *This medication was added to the Ryan White Program Prescription Drug Formulary as a cost saving measure to prevent hospitalization and fracture complication for patients (clients). This medication is for treatment and prevention of osteoporosis.* |
| **OO** | *The Florida Department of Health issued an Interoffice Memorandum, dated October 1, 2012, with information regarding the approval by the U.S. Food and Drug Administration (FDA) of Stribild (Elvitegravir/Cobicistat/Emtricitabine/Tenofovir Disoproxil Fumarate), for the treatment of human immunodeficiency virus type 1 (HIV-1) infection in adults who are antiretroviral treatment-naïve. This pill also contains a pharmacologic boosting agent (cobicistat) used to prolong the effect of elvitegravir.* |
| **PP** | *Colonoscopies are a life-saving procedure and without this preparatory medication the procedure cannot be performed.* |
| **QQ** | *For reporting/tracking purposes only, this product is classified as over-the-counter (OTC).* |
| **RR** | *For reporting/tracking purposes only, some formulations of this medication are available over-the-counter (OTC).* |
| **SS** | *The Florida Department of Health issued an Interoffice Memorandum, dated September 27, 2013, with information regarding the approval by the U.S. Food and Drug Administration (FDA) of Tivicay (dolutegravir), for the treatment of human immunodeficiency virus type 1 (HIV-1) infection in adults who are antiretroviral treatment-naïve.* |

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| **TT** | *For new and renewal prescriptions of Vitamin B-12 (cyanocobalamin), lab work must accompany the prescription indicating the Vitamin B-12 levels are less than 400 picograms per milliliter in order for the medication to be dispensed.* |
| **UU** | *Per HHS guidelines it is recommended that abacavir-naïve patients be tested for HLA-B*5701 hypersensitivity. HLA-B*5701 positive patients should not be prescribed this medication (Epzicom, Ziagen, or Trizivir). A copy of the test results should be placed in the patient's file. The HLA-B*5701 test should only be conducted once.* |
| **VV** | *The Florida Department of Health issued an electronic mail message, dated October 29, 2014, with information regarding the approval by the U.S. Food and Drug Administration (FDA) of Triumeq (abacavir/dolutegravir/lamivudine), for the treatment of HIV-1 infection.* |