Ryan White Program
Service Delivery Guidelines
Fiscal Year 2016
(Year 26)

Section V –
Letters of Nutritional Assessment and Medical Necessity

Miami-Dade County
Office of Management and Budget
Grants Coordination

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RYAN WHITE PROGRAM NUTRITIONAL ASSESSMENT LETTER FOR FOOD BANK SERVICES

[THIS LETTER IS REQUIRED FOR EXTENDED FOOD BANK SERVICES OVER AND ABOVE THE INITIAL 16 OCCURRENCES (VISITS)]

(THIS DOCUMENT IS TO BE COMPLETED BY A LICENSED MEDICAL PROVIDER OR A REGISTERED DIETITIAN NOT ASSOCIATED WITH THE PART A FOOD BANK PROVIDER.)

DATE:_____

As the **licensed medical provider** for _____, it is my professional opinion that he/she requires an **extension** of food bank assistance.

OR

As a **registered dietitian** who has completed an assessment of _____, it is my professional opinion that he/she requires an **extension** of food bank assistance.

The client has the following **severe** change of status (mark all that apply):

__New HIV-related diagnosis/symptom (please describe) e.g. OI, AIDS diagnosis,etc._____

__Wasting syndrome

__Protein imbalance

__Recent chemotherapy

__Recent hospitalization

__Other medical reasons:_____

Please specify number of occurrences (maximum 16 additional occurrences within the current Ryan White Part A fiscal year): _____

This assistance will maintain the patient's health by providing a balanced, adequate diet, which the patient is currently not receiving.

Licensed Medical Provider Signature_____ Name_____

Print License #_____

OR

Registered Dietitian Signature_____ Name_____

Registered Dietitian License #_____

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.

Rev. 3/1/2015

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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)

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Rev. 3/1/2014

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RYAN WHITE PROGRAM
Letter of Medical Necessity to Accompany Prescription for Tipranavir (Aptivus®)

Date: _____

As the prescribing healthcare provider for _____, I consider it to be medically necessary to add Tipranavir (Aptivus®) to this patient's antiretroviral regimen.

In addition, I hereby certify that the following criteria have been met:

1. The patient has failed treatment with Lopinavir/ritonavir (Kaletra®) and all three classes of antiretrovirals;

-AND-

2. I have fully discussed all issues and consequences related to non-adherence with the patient.

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.

Rev. 3/1/2014

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RYAN WHITE PROGRAM
Letter of Medical Necessity to Accompany Prescription for Enfuvirtide (Fuzeon®)

Date: _____

As the primary medical provider for _____, I consider it to be medically necessary to add Enfuvirtide (Fuzeon®) to this patient's antiretroviral regimen.

This patient has been on Enfuvirtide (Fuzeon®) through another funding source but this funding source is no longer available. This condition necessitates Ryan White Program coverage for continuity of care.

In addition, the patient meets one (1) of the following (check-off the appropriate criteria below):

☐ 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.

-OR-

☐ The patient is not eligible for ADAP and must be covered under the Ryan White Program pending another payment source. A new prescription is allowed for a maximum of **90 days** and no refill authorizations are accepted.

_____, M.D.

_____ Print M.D.'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.

Rev. 3/1/2014

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LAB TEST

RYAN WHITE PROGRAM
Letter of Medical Necessity for the Highly Sensitive Tropism Assay required to prescribe Maraviroc (Selzentry ®)

(Required only when the cost of the assay is not covered by any other funding source, including ViiV Healthcare.)

Date: _____

As the primary care physician treating_____, I intend to add Maraviroc (Selzentry) to this patient's antiretroviral regimen which will contain the following two other agents: _____ and _____.

I certify the client (patient) is not eligible for ViiV Healthcare's Tropism Access Program (TAP) or any other payment source;

I understand the Highly Sensitive Tropism Assay may only be ordered under the following conditions:

1. The above criterion has been met and is 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 satisfactorily adherent with his/her current ART regimen;

   and

3. Patient does not have a history of dual/mixed tropism.

Sincerely,

_____, MD/DO/ARNP/PA

_____	_____
Print MD/DO/ARNP/PA 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.

Rev. 11/10/2014

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RYAN WHITE PROGRAM
Letter of Medical Necessity for Neupogen® (Filgrastim)

Recipient's Full Name:_____ Date of Birth: _____ /_____ /_____

Prescriber Full Name:_____ Prescriber License #: (MD,OS,RN)_____

Prescriber Telephone #:_____ Prescriber Fax #:_____

Drug Strength: _____

Please check below the diagnosis or indication for this product:

☐ Severe neutropenia in AIDS patients on antiretroviral therapy

☐ Severe Chronic Neutropenia: ☐ congenital ☐ cyclic ☐ idiopathic

☐ Cancer patients with HIV/AIDS receiving myelosuppressive chemotherapy

Select one of the following:

New Therapy ☐ **OR** Continuation of Therapy ☐

Lab Test Date: _____ Absolute Neutrophil Count: _____ cells/mm3

What is the date range of therapy? Begin Date: _____ End Date: _____

Indicate dosage and frequency of dosing: _____

Prescriber's Signature: _____

Please attach a copy of the original prescription and lab results dated within the last two (2) months.

Fax information to:

Ryan White Program-funded Pharmacy	Phone Number	Fax Number
AIDS Healthcare Foundation (NW 170th St.)	(305) 758-1984	(305) 758-8714
AIDS Healthcare Foundation (Biscayne Blvd.)	(305) 764-3780	(305) 764-3784
AIDS Healthcare Foundation (Miami Beach)	(305) 538-5914	(305) 538-1730
AIDS Healthcare Foundation (S. Miami Ave.)	(305) 534-1294	(305) 534-8311
Citrus Health Network	(305) 825-0300, Ext. 2770	(305) 556-2580
Community Health of South Florida (Doris Ison)	(305) 253-5100	(305) 254-7795
Community Health of South Florida (MLKJCC)	(305) 248-4334	(305) 246-1016
Miami Beach Community Health Ctr (Alton Rd.)	(305) 538-8835, Option 41	(305) 695-2156
Miami Beach Community Health Ctr. (Bev. Press)	(305) 538-8835, Option 42	(305) 867-4312
Miami Beach Community Health Ctr. (North)	(305) 538-8835, Option 43	(305) 695-2168
Public Health Trust / Jackson Health System	(305) 585-5890	(305) 585-0088

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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RYAN WHITE PROGRAM
Letter of Medical Necessity for Procrit® or Epogen® (both Epoetin Alpha)

Recipient's Full Name:_____ Date of Birth: _____ /_____ /_____

Prescriber Full Name:_____ Prescriber License #: (MD,OS,RN)_____

Prescriber Telephone #:_____ Prescriber Fax #:_____

Drug Strength: _____

Please check below the diagnosis or indication for this product:

☐ Anemia associated with HIV

☐ Anemia associated with renal failure if patient is not on dialysis

☐Anemia associated with chemotherapy

☐Other _____

Select one of the following:

New Therapy ☐ **OR** Continuation of Therapy ☐

Does the patient have active gastrointestinal bleeding? ☐ YES **OR** ☐ NO

Lab Test Date:_____ Hematocrit:_____% Hemoglobin:_____g/dl

Indicate dosage and frequency of dosing: _____

Prescriber's Signature: _____

Please attach a copy of the original prescription and lab results dated within the last two (2) months.

Fax information to:

Ryan White Program-funded Pharmacy	Phone Number	Fax Number
AIDS Healthcare Foundation (NW 170th St.)	(305) 758-1984	(305) 758-8714
AIDS Healthcare Foundation (Biscayne Blvd.)	(305) 764-3780	(305) 764-3784
AIDS Healthcare Foundation (Miami Beach)	(305) 538-5914	(305) 538-1730
AIDS Healthcare Foundation (S. Miami Ave.)	(305) 534-1294	(305) 534-8311
Citrus Health Network	(305) 825-0300, Ext. 2770	(305) 556-2580
Community Health of South Florida (Doris Ison)	(305) 253-5100	(305) 254-7795
Community Health of South Florida (MLKJCC)	(305) 248-4334	(305) 246-1016
Miami Beach Community Health Ctr (Alton Rd.)	(305) 538-8835, Option 41	(305) 695-2156
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RYAN WHITE PROGRAM
Letter of Medical Necessity
for Roxicodone (Oxycodone) and Percocet (Oxycodone/APAP)

Date:_____

As the primary care physician treating _____and in accordance with **F.A.C. 64B8-9.013** [1] it is my considered opinion that (check **one** of the following)

☐ Roxicodone (Oxycodone)

☐ Percocet (Oxycodone/APAP) 5/325 *generic only*

is medically necessary for this patient.

The patient's diagnosis related to the reason for prescribing this medication is _____. The above medication will be prescribed for _____ (length of time) at a strength of _____ with a frequency of _____(e.g. bid).

- I have documented that other pain medications have been used and have failed or were not tolerated.
- I have discussed the issue of dependency with the patient.

I attest the above conditions have been met and are fully documented in the patient's medical record.

Sincerely,

_____, M.D./D.O.

_____ Print M.D./D.O. name

_____ Florida Medical License # (ME#)

_____ Patient's 10 Digit Medicaid # (if applicable)

_____ Patient's CIS # (ID number 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.

Rev. 3/1/2014

[1] Florida Administrative Code 64B8-9.013 Standards for the Use of Controlled Substances for the Treatment of Pain. Specific Authority Florida Statute 458.309 and 458.331.

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64B8-9.013 Standards for the Use of Controlled Substances for the Treatment of Pain.

(1) Pain management principles.

(a) The Board of Medicine recognizes that principles of quality medical practice dictate that the people of the State of Florida have access to appropriate and effective pain relief. The appropriate application of up-to-date knowledge and treatment modalities can serve to improve the quality of life for those patients who suffer from pain as well as reduce the morbidity and costs associated with untreated or inappropriately treated pain. The Board encourages physicians to view effective pain management as a part of quality medical practice for all patients with pain, acute or chronic, and it is especially important for patients who experience pain as a result of terminal illness. All physicians should become knowledgeable about effective methods of pain treatment as well as statutory requirements for prescribing controlled substances.

(b) Inadequate pain control may result from physicians' lack of knowledge about pain management or an inadequate understanding of addiction. Fears of investigation or sanction by federal, state, and local regulatory agencies may also result in inappropriate or inadequate treatment of chronic pain patients. Physicians should not fear disciplinary action from the Board or other state regulatory or enforcement agencies for prescribing, dispensing, or administering controlled substances including opioid analgesics, for a legitimate medical purpose and that is supported by appropriate documentation establishing a valid medical need and treatment plan. Accordingly, these standards have been developed to clarify the Board's position on pain control, specifically as related to the use of controlled substances, to alleviate physician uncertainty and to encourage better pain management.

(c) The Board recognizes that controlled substances, including opioid analgesics, may be essential in the treatment of acute pain due to trauma or surgery and chronic pain, whether due to cancer or non-cancer origins. The medical management of pain including intractable pain should be based on current knowledge and research and includes the use of both pharmacologic and non-pharmacologic modalities. Pain should be assessed and treated promptly, and the quantity and frequency of doses should be adjusted according to the intensity and duration of the pain. Physicians should recognize that tolerance and physical dependence are normal consequences of sustained use of opioid analgesics and are not synonymous with addiction.

(d) The Board of Medicine is obligated under the laws of the State of Florida to protect the public health and safety. The Board recognizes that inappropriate prescribing of controlled substances, including opioid analgesics, may lead to drug diversion and abuse by individuals who seek them for other than legitimate medical use. Physicians should be diligent in preventing the diversion of drugs for illegitimate purposes.

(e) The Board will consider prescribing, ordering, administering, or dispensing controlled substances for pain to be for a legitimate medical purpose if based on accepted scientific knowledge of the treatment of pain or if based on sound clinical grounds. All such prescribing must be based on clear documentation of unrelieved pain and in compliance with applicable state or federal law.

(f) Each case of prescribing for pain will be evaluated on an individual basis. The Board will not take disciplinary action against a physician for failing to adhere strictly to the provisions of these standards, if good cause is shown for such deviation. The physician's conduct will be evaluated to a great extent by the treatment outcome, taking into account whether the drug used is medically and/or pharmacologically recognized to be appropriate for the diagnosis, the patient's individual needs including any improvement in functioning, and recognizing that some types of pain cannot be completely relieved.

(g) The Board will judge the validity of prescribing based on the physician's treatment of the patient and on available documentation, rather than on the quantity and chronicity of prescribing. The goal is to control the patient's pain for its duration while effectively addressing other aspects of the patient's functioning, including physical, psychological, social, and work-related factors. The following standards are not intended to define complete or best practice, but rather to communicate what the Board considers to be within the boundaries of professional practice.

(2) Definitions.

(a) Acute Pain. For the purpose of this rule, "acute pain" is defined as the normal, predicted physiological response to an adverse chemical, thermal, or mechanical stimulus and is associated with surgery, trauma, and acute illness. It is generally time-limited and is responsive to opioid therapy, among other therapies.

(b) Addiction. For the purpose of this rule, "addiction" is defined as a neurobehavioral syndrome with genetic and environmental influences that results in psychological dependence on the use of substances for their psychic effects and is characterized by compulsive use despite harm. Addiction may also be referred to by terms such as "drug dependence" and "psychological dependence." Physical dependence and tolerance are normal physiological consequences of extended opioid therapy for pain and should not be considered addiction.

Effective 10/17/2010

(c) Analgesic Tolerance. For the purpose of this rule, "analgesic tolerance" is defined as the need to increase the dose of opioid to achieve the same level of analgesia. Analgesic tolerance may or may not be evident during opioid treatment and does not equate with addiction.

(d) Chronic Pain. For the purpose of this rule, "chronic pain" is defined as a pain state which is persistent.

(e) Pain. For the purpose of this rule, "pain" is defined as an unpleasant sensory and emotional experience associated with actual or potential tissue damage or described in terms of such damage.

(f) Physical Dependence. For the purpose of this rule, "physical dependence" on a controlled substance is defined as a physiologic state of neuro-adaptation which is characterized by the emergence of a withdrawal syndrome if drug use is stopped or decreased abruptly, or if an antagonist is administered. Physical dependence is an expected result of opioid use. Physical dependence, by itself, does not equate with addiction.

(g) Pseudoaddiction. For the purpose of this rule, "pseudoaddiction" is defined as a pattern of drug-seeking behavior of pain patients who are receiving inadequate pain management that can be mistaken for addiction.

(h) Substance Abuse. For the purpose of this rule, "substance abuse" is defined as the use of any substances for non-therapeutic purposes or use of medication for purposes other than those for which it is prescribed.

(i) Tolerance. For the purpose of this rule, "tolerance" is defined as a physiologic state resulting from regular use of a drug in which an increased dosage is needed to produce the same effect, or a reduced effect is observed with a constant dose.

(3) Standards. The Board has adopted the following standards for the use of controlled substances for pain control:

(a) Evaluation of the Patient. A complete medical history and physical examination must be conducted and documented in the medical record. The medical record shall document the nature and intensity of the pain, current and past treatments for pain, underlying or coexisting diseases or conditions, the effect of the pain on physical and psychological function, and history of substance abuse. The medical record also shall document the presence of one or more recognized medical indications for the use of a controlled substance.

(b) Treatment Plan. The written treatment plan shall state objectives that will be used to determine treatment success, such as pain relief and improved physical and psychosocial function, and shall indicate if any further diagnostic evaluations or other treatments are planned. After treatment begins, the physician shall adjust drug therapy, if necessary, to the individual medical needs of each patient. Other treatment modalities or a rehabilitation program may be necessary depending on the etiology of the pain and the extent to which the pain is associated with physical and psychosocial impairment.

(c) Informed Consent and Agreement for Treatment. The physician shall discuss the risks and benefits of the use of controlled substances with the patient, persons designated by the patient, or with the patient's surrogate or guardian if the patient is incompetent. The patient shall receive prescriptions from one physician and one pharmacy where possible. If the patient is determined to be at high risk for medication abuse or have a history of substance abuse, the physician shall employ the use of a written agreement between physician and patient outlining patient responsibilities, including, but not limited to:

1. Urine/serum medication levels screening when requested;
2. Number and frequency of all prescription refills; and
3. Reasons for which drug therapy may be discontinued (i.e., violation of agreement).

(d) Periodic Review. Based on the individual circumstances of the patient, the physician shall review the course of treatment and any new information about the etiology of the pain. Continuation or modification of therapy shall depend on the physician's evaluation of the patient's progress. If treatment goals are not being achieved, despite medication adjustments, the physician shall reevaluate the appropriateness of continued treatment. The physician shall monitor patient compliance in medication usage and related treatment plans.

(e) Consultation. The physician shall be willing to refer the patient as necessary for additional evaluation and treatment in order to achieve treatment objectives. Special attention must be given to those pain patients who are at risk for misusing their medications and those whose living arrangements pose a risk for medication misuse or diversion. The management of pain in patients with a history of substance abuse or with a comorbid psychiatric disorder requires extra care, monitoring, and documentation, and may require consultation with or referral to an expert in the management of such patients.

(f) Medical Records. The physician is required to keep accurate and complete records to include, but not be limited to:

1. The complete medical history and a physical examination, including history of drug abuse or dependence, as appropriate;
2. Diagnostic, therapeutic, and laboratory results;
3. Evaluations and consultations;

4. Treatment objectives;
5. Tiscussion of risks and benefits;
6. Treatments;
7. Medications (including date, type, dosage, and quantity prescribed);
8. Instructions and agreements;
9. Drug testing results; and
10. Periodic reviews. Records must remain current, maintained in an accessible manner, readily available for review, and must be in full compliance with Rule 64B8-9.003, F.A.C, and Section 458.331(1)(m), F.S.

Records must remain current and be maintained in an accessible manner and readily available for review.

(g) Compliance with Controlled Substances Laws and Regulations. To prescribe, dispense, or administer controlled substances, the physician must be licensed in the state and comply with applicable federal and state regulations. Physicians are referred to the Physicians Manual: An Informational Outline of the Controlled Substances Act of 1970, published by the U.S. Drug Enforcement Agency, for specific rules governing controlled substances as well as applicable state regulations.

Rulemaking Authority 458.309(1), 458.331(1)(v) FS. Law Implemented 458.326, 458.331(1)(g), (t), (v) FS. History–New 12-21-99, Amended 11-10-02, 10-19-03, 10-17-10.

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RYAN WHITE PROGRAM
Letter of Medical Necessity for Sporanox (Itraconazole)

Date:_____

As the primary care physician treating _____, I consider it medically necessary to prescribe Sporanox (Itraconazole). The medication will be utilized to treat **ONLY** one of the following two conditions (please check one box):

☐	Histoplasmosis
☐	Aspergillosis

The diagnosis above is fully documented in the patient's medical record.

Sincerely,

_____, M.D./D.O.

_____ Print M.D./D.O. 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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RYAN WHITE PROGRAM
Letter of Medical Necessity (LOMN) for Testosterone Supplementation
(A LOMN must accompany each prescription)

Date: _____

As the prescribing practitioner treating_____, I intend to place this patient on testosterone supplementation (duration may NOT exceed 12 months). I have educated the patient on the consequences of testosterone supplementation and have explained the risks associated with this therapy, including venous blood clots, and increased risk of heart attacks and strokes.

I certify that the patient (mark all that apply):

___has a documented low (<350 ng/dL) testosterone lab level at initiation of therapy;

OR

___has a documented history of testosterone therapy but has discontinued therapy for 60 calendar days to re-evaluate levels and still has a documented low (<350 ng/dL) testosterone lab level.

AND/OR

___has primary hypogonadism, in which there is low testosterone accompanied by increased follicle-stimulated hormone and increased luteinizing hormone. Common causes include: Klinefelter's syndrome, anorchism, undescended testicles, mumps orchitis, hemochromatosis, injury to testicles, cancer treatment, and normal aging.

AND/OR

___has secondary hypogonadism, in which there is low testosterone accompanied by low to normal follicle-stimulated hormone and luteinizing hormone. Common causes include: Kallmann syndrome, pituitary disorders, inflammatory diseases, HIV/AIDS, medications, obesity, and stress-induced hypogonadism.

AND

___is physically symptomatic (e.g. malaise, fatigue, lethargy, muscle loss, depression, decreased bone mass or bone mineral density, etc.).

The following restriction is placed on the medications: Maximum dose is 400 mg per month unless clinically indicated per labs.

_____ , M.D./D.O.

_____ Print M.D./D.O. name

_____ Florida medical license # (MEO#)

_____ 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 addressed to 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 dietician, 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 files (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.

Rev. 11/9/2015

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RYAN WHITE PROGRAM NUTRITIONAL SUPPLEMENTS REFERRAL
Physician Letter of Medical Necessity for Supplementation in ADULTS
(This form serves as a referral; the medical provider should maintain a copy of this form in the patient file.)

Date: _____

As the licensed medical provider for_____, who has a diagnosis of HIV/AIDS, it is my considered opinion that he/she requires and meets the criteria indicated below for nutritional supplements.

Patient must meet at least two (2) of the criteria listed below for a high protein and/or high carbohydrate nutritional supplement. (Dispensing limited to 4 bottles of any combination per month)

Please check all that apply:

High Protein Criteria*	**High Carbohydrate Criteria****
__Current body weight < 10% IBW/UBW	
__Body Mass Index (BMI) <20	
__Recent illness/hospitalization that will interfere with patient's ability to consume or tolerate adequate non-supplemental nutrition	
__Dysphagia and/or odonyphagia where commercial supplements are the only source of nutrition tolerated	
__Inadequate living conditions or inability to buy/prepare meals	
__ Inability to understand and or follow nutritional recommendations	
Weight loss of: __5% of the initial/baseline weight over the past month -OR- __7.5% over the past 3 months	Weight loss of: __More than 10% weight loss within the last 6 months
__Body Cell Mass (BCM) < 40% (MALES) or BCM < 35% (FEMALE) of IBW	__Failure to gain/maintain weight in the past when following a dietary regimen to promote weight gain
__Diarrhea/malabsorption with > 3 large, liquid stools/day	
__Serum albumin < 3.5g/dl	
***Do not dispense multivitamins if patient receives Progain.**	****Not indicated for use in diabetic patients.**

I understand this patient's nutrition status must be evaluated by a Dietitian/Nutritionist no less than every 90 days. Re-evaluation is **due** at_____. *(Number of refills authorized cannot exceed this period of time.)*
mm/dd/yy

I believe that nutritional supplements are medically indicated in this case and I have referred this patient for a professional Nutritional Assessment at_____.
Location

Sincerely,

_____, M. D./ D.O./ ARNP/ PA-C
SIGNATURE
(Physician, Nurse Practitioner or Physician Assistant)

_____ _____
PRINT NAME Florida Medical License #
(Physician, Nurse Practitioner or Physician Assistant)

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RYAN WHITE PROGRAM NUTRITIONAL SUPPLEMENTS REFERRAL

(To be completed by the dietitian; the original of page 1 and a copy of page 2 must be maintained in the dietitian's patient file. A copy of page 1 and the original of page 2 should be forwarded to the pharmacy.)

Patient Name:_____ Date: _____

Please document patient:

Height:_____

ABW: _____ □ Lbs □ Kgs

IBW: _____ □ Lbs □ Kgs

UBW: _____ □ Lbs □ Kgs

Total Calories needed:_____g/kg/per day

Total Protein needed:_____g/kg/per day

Total Carbohydrates needed:_____g/kg/per day

Days Supply:_____

PRESCRIPTION

NOTE: 1 Serving = 2 Scoops

□ Progain Powder - ___No. of **SERVINGS per DAY** □ Vanilla □ Chocolate

(HIGH Carbohydrate)

Number of Refills Authorized _____

(Number of refills authorized cannot exceed period of time for re-evaluation every 90 days by nutritionist/dietitian)

□ IgG Pure - ___No. of **SERVINGS per DAY** (Only natural flavor available)

(HIGH Protein)

Number of Refills Authorized _____

(Number of refills authorized cannot exceed period of time for re-evaluation every 90 days by nutritionist/dietitian)

NUTRITIONAL PLAN FOR SUPPLEMENTS

I. INITIAL Consultation: Date: _____ Weight: _____

Patient assessed/instructed by Registered Dietitian/Nutritionist: **(Please check the appropriate box)**

☐ Nutritional supplements **recommended** ☐ Nutritional supplements **NOT** recommended

II. FOLLOW-UP Visit: Date:_____ Weight: _____

Patient re-assessed for progress: **(Please check the appropriate box)**

☐ Nutritional supplements **continued** ☐ Nutritional supplements **discontinued**

III. ADDITIONAL FOLLOW-UP Visit: Date: _____ Weight: _____

Patient re-assessed for progress: **(Please check the appropriate box)**

☐ Nutritional supplements **continued** ☐ Nutritional supplements **discontinued**

_____

SIGNATURE
(Registered Dietitian/Nutritionist)

_____ _____

PRINT NAME Dietitian/Nutritionist Florida License #
(Registered Dietitian/Nutritionist)

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