Division: Pharmacy Policy	Subject: State of Florida's Agency for Health Care Administration's Prior Authorization Criteria
Original Development Date: Original Effective Date: Revision Date:	September 12, 2012 February 13, 2013; December 30, 2013, January 22, 2015, November 16, 2015

EDURANT®

(For Treatment Experienced Patients)

LENGTH OF AUTHORIZATION: Up to 365 days

REVIEW CRITERIA:

INITIATION OF THERAPY

1. If patient has a confirmed diagnosis of HIV (per medical records or diagnosis codes), is treatment naïve (no history of HIV/AIDS related antiretroviral (ARV) therapy), and has HIV RNA-1 ≤ 100,000 copies/mL then approve. If patient has a confirmed diagnosis, but is not treatment naïve then proceed to #2. If the patient does not have a confirmed diagnosis, then deny.

2. Patient must have a viral count (HIV RNA) ≥ 200 copies/mm3. *(Provider must supply copies of the last two official viral load lab results dated within the past six months.)*

3. Patient must have had treatment failure of antiretroviral therapy.

- NOTES:
  - Failure is defined as lack of response as evidenced by viral load.
  - Failure due to noncompliance is not reason for approval.
  - Requests due to convenience are not a reason for approval.
  - Medication intolerance due to adverse side effects may not be a reason to approve the requested therapy. The reviewer should look for the patient's tolerance of the current regimen and the severity and duration of side effects. Management strategies for intolerance in the absence of drug resistance may include:
    - using symptomatic treatment (e.g., antiemetics, antidiarrheals)
    - changing one ARV to another within the same drug class, if needed (e.g., change to tenofovir [TDF] or abacavir [ABC] for zidovudine [ZDV]-related toxicities; change to nevirapine [NVP] or etravirine [ETR] for efavirenz [EFV]-related toxicities)
    - changing from one drug class to another (e.g., from a non-nucleoside reverse transcriptase inhibitor [NNRTI] to a protease inhibitor [PI], from enfuvirtide [T-20] to raltegravir [RAL]) if necessary and no prior drug resistance is suspected
    - Review food/fasting requirements for each medication. See if patient taking with food or not. *(e.g. Adverse effect may be resolved or improved if medication is taken with food.)*

4. If viral load > 1000 copies/mL drug resistance tests (dated within the past six months) must be submitted.
   - NOTES:
     - If a provider is able to provide this test then it is evident that the patient is being managed for suboptimal viral load reduction.
     - FYI: Routine genotypic or phenotypic testing (drug resistance testing) gives information relevant for selecting nucleoside reverse transcriptase inhibitors (NRTIs), NNRTIs, and PIs. Additional drug-resistance tests for patients experiencing failure on fusion inhibitors and/or integrase strand transfer inhibitors (INSTIs) and viral tropism tests for patients experiencing failure on a CCR5 antagonist also are available.
5. The quantity should not exceed one tablet per day.
6. Recipients must be ≥ 12 years of age.

CONTINUATION OF THERAPY

1. Patient must have had previous history (per claims or medical records history) of medication in the past 365 days.
2. The quantity should not exceed one tablet per day.
3. Recipients must be ≥ 12 years of age.

Prior authorization requests for **Edurant in a treatment experienced patient must be submitted on the **Miscellaneous Pharmacy Prior Authorization Form** which can be downloaded from http://ahca.myflorida.com/Medicaid/Prescribed_Drug/pharm_thera/paforms.shtml*

**Prior authorization requests related to a lack of a diagnosis code on record or for HIV diagnosis verification must be submitted on the HIV Diagnosis Verification Form.*