

## Criteria for Formulary Use of Darunavir

VA Pharmacy Benefits Management Strategic Healthcare Group and Medical Advisory Panel

*The following recommendations are based on current medical evidence and expert opinion from clinicians. The content of the document is dynamic and will be revised as new clinical data becomes available. The purpose of this document is to assist practitioners in clinical decision-making, to standardize and improve the quality of patient care, and to promote cost-effective drug prescribing. The clinician should utilize this guidance and interpret it in the clinical context of individual patient situations*

Refer to the National PBM Drug Monograph Darunavir (Prezista®) for recommendations on dosing, precautions, and monitoring

<b>Criteria I</b>	<b>#1</b>
Highly treatment-experienced patients (including at least 1 prior failed PI regimen) <b>OR</b> Documented evidence of resistance to other PI regimens	<input type="checkbox"/> Yes <input type="checkbox"/> No  <i>If Yes to #1, go to #2. If No to #1 patient is not eligible</i>
<b>Criteria II</b>	<b>#2</b>
Evidence of virologic failure (documented by a viral load > 1,000 copies/ml) <b>AND</b> Evidence of genotypic or phenotypic resistance on their current PI regimen	<input type="checkbox"/> Yes <input type="checkbox"/> No  <i>If Yes to #2, go to #3 If No to #2, patient is not eligible</i>
<b>Criteria III</b>	<b>#3</b>
Genotypic and/or phenotypic testing performed and results, along with treatment history, used to guide the use of darunavir. Presence of three or more of the following mutations is associated with decreased darunavir efficacy: V11I, V32I, L33F, I47V, I50V, I54L/M, G73S, L76V, I84V, and L89V, as is >40-fold change in sensitivity.	<input type="checkbox"/> Yes <input type="checkbox"/> No  <i>If Yes to #3, go to #4 If No to #3, patient is not eligible</i>
<b>Criteria IV</b>	<b>#4</b>
Able to tolerate low dose ritonavir (100mg) twice a day	<input type="checkbox"/> Yes <input type="checkbox"/> No  <i>If Yes to #4, go to #5 If No to #4, patient is not eligible</i>
<b>Criteria V</b>	<b>#5</b>
Able to construct a multi-drug regimen that includes, preferably, at least one additional active anti-retroviral drug (if available) in addition to darunavir/ritonavir	<input type="checkbox"/> Yes <input type="checkbox"/> No  <i>If Yes to #5, go to #6 If No to #5, patient is not eligible</i>
<b>Exclusion Criteria</b>	<b>#6</b>
Co-administration with the following medications: <input type="checkbox"/> Cisapride <input type="checkbox"/> Astemizole <input type="checkbox"/> Terfenadine <input type="checkbox"/> Ergot derivatives <input type="checkbox"/> Pimozide <input type="checkbox"/> Triazolam <input type="checkbox"/> Midazolam	<input type="checkbox"/> Yes <input type="checkbox"/> No  <i>If No to all conditions in #6 and Yes to #1-5, patient is eligible for darunavir with ritonavir.</i>

Approved by Physician: \_\_\_\_\_

Date/Time \_\_\_\_\_

Updated versions may be found at <http://vaww.pbm.va.gov> or [www.pbm.va.gov](http://www.pbm.va.gov)  
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