Reference number(s)
6160-D

This document applies to the following:

Formulary	Applies
Standard Control (SF)	☑
Standard Control – Choice (SCCF)	☑
Preferred Drug Plan Design (PDPD)	☐
Advanced Control Specialty (ACSF)	☑
Advanced Control Specialty – Choice (ACSCF)	☑
Managed Medicaid Template (MMT)	☐
Marketplace (MF)	☐
Aetna Small Group Affordable Care Act (SG ACA) Aetna Health Exchange (AHE)	☐
Aetna Individual Lives (IVL)	☐
Value (VF)	☐

Formulary	Applies
New to Market (NTM)	☐
Standard Formulary Chart (SFC)	☐
Basic Control Chart Preferred Drug Plan Design (BCC PDPD)	☐
Advanced Control Specialty Formulary Chart (ACSFC)	☐
Value Formulary Chart (VFC)	☐
Medical Benefit	☐
Medical Benefit: Advanced Biosimilars First	☐
Medical Benefit: Managed Medicaid (MMMB)	☐
Medicare Part B	☐
Medicare Part B: Advanced Biosimilars First	☐

Exceptions Criteria
Human Immunodeficiency Virus (HIV) Agents - Protease Inhibitors

This document informs prescribers of preferred products and provides an exception process for targeted products through prior authorization.

These criteria were developed to align with the following: Standard Control Formulary (SF), Standard Control Choice Formulary (SCCF), Advanced Control Specialty Formulary (ACSF), and Advanced Control Specialty – Choice Formulary (ACSCF).

Plan Design Summary

This program applies to the human immunodeficiency virus (HIV) protease inhibitor products specified in this document. Coverage for the targeted products is provided based on clinical circumstances that would exclude the use of the preferred products and may be based on previous use of a product. The coverage review process will ascertain situations where a clinical exception can be made. This program applies to members who are new to treatment with Prezista suspension or Reyataz powder for the first time. This program also applies to all members requesting treatment with Kaletra, Norvir, Prezista tablets, Reyataz capsules, and Viracept.

Each referral is reviewed based on all utilization management (UM) programs implemented for the client.

Table. HIV Protease Inhibitors

Medications considered formulary or preferred on your plan may still require a clinical prior authorization review.

	Products
Preferred	• atazanavir (generic) • darunavir (generic) • lopinavir-ritonavir (generic) • ritonavir (generic)
Target	• Kaletra (lopinavir-ritonavir) • Norvir (ritonavir) • Prezista (darunavir) • Reyataz (atazanavir) • Viracept (nelfinavir)

Exception Criteria

This document applies to members requesting treatment for an indication that is FDA-approved for the preferred products.

Norvir

Coverage for Norvir is provided when the member meets either of the following criteria:

- The requested product is Norvir powder packets and the member is unable to reliably swallow tablets.
- Member has had a documented intolerable adverse event to generic ritonavir, and the adverse event was not an expected adverse event attributed to the active ingredient as described in the prescribing information.

Prezista

Coverage for Prezista is provided when the member meets either of the following criteria:

- Member is currently receiving treatment with Prezista suspension, excluding when Prezista suspension is obtained as samples or via manufacturer's patient assistance programs.
- Member meets both of the following criteria:
  - Member has had a documented intolerable adverse event to generic darunavir, and the adverse event was not an expected adverse event attributed to the active ingredient as described in the prescribing information.
  - Member meets either of the following:
    - Member is less than 6 years of age or the member weighs less than 15 kg.
    - Member is 6 years of age or older and the member weighs at least 15 kg, and has a documented inadequate response, intolerable adverse event, or contraindication to atazanavir.

Reyataz

Coverage for Reyataz is provided when the member meets any of the following criteria:

- Member is currently receiving treatment with Reyataz powder, excluding when Reyataz powder is obtained as samples or via manufacturer's patient assistance programs.
- The requested product is Reyataz powder and the member meets any of the following criteria:
  - Member is less than 6 years of age.
  - Member weighs less than 15 kg.
  - Member is unable to reliably swallow capsules.
- Member is less than 3 years of age or the member weighs less than 10 kg, and the member has had a documented intolerable adverse event to generic atazanavir, and the adverse event was not an expected adverse event attributed to the active ingredient as described in the prescribing information.
- Member is 3 years of age or older and the member weighs at least 10 kg, and meets both of the following criteria:
  - Member has had a documented intolerable adverse event to generic atazanavir, and the adverse event was not an expected adverse event attributed to the active ingredient as described in the prescribing information.
  - Member has a documented inadequate response, intolerable adverse event, or contraindication to darunavir.

Kaletra

Coverage for Kaletra is provided when the member meets both of the following criteria:

- Member has had a documented intolerable adverse event to generic lopinavir-ritonavir, and the adverse event was not an expected adverse event attributed to the active ingredient as described in the prescribing information.
- Member meets any of the following criteria:
  - Member is less than 3 years of age or the member weighs less than 10 kg.
  - Member is 3 years of age to less than 6 years of age or the member weighs less than 15 kg, and has a documented inadequate response, intolerable adverse event, or contraindication to darunavir.
  - Member is 6 years of age or older and the member weighs at least 15 kg, and has a documented inadequate response, intolerable adverse event, or contraindication to both of the following:
    - atazanavir
    - darunavir

Viracept

Coverage for Viracept is provided when the member meets any of the following criteria:

- Member is less than 3 years of age, and has a documented inadequate response, intolerable adverse event, or contraindication to lopinavir-ritonavir.
- Member is 3 years of age to less than 6 years of age or the member weighs less than 15 kg, and has a documented inadequate response, intolerable adverse event, or contraindication to both of the following:
  - darunavir
  - lopinavir-ritonavir

- Member is 6 years of age or older and the member weighs at least 15 kg and has a documented inadequate response, intolerable adverse event, or contraindication to all of the following:
    - atazanavir
    - darunavir
    - lopinavir-ritonavir

References

1. Atazanavir [package insert]. East Windsor, NJ: Aurobindo Pharma USA, Inc.; January 2024.
2. Darunavir [package insert]. Baltimore, MD: Lupin Pharmaceuticals, Inc.; January 2024.
3. Kaletra [package insert]. North Chicago, IL: AbbVie Inc.; April 2023.
4. Lopinavir-ritonavir [package insert]. Piscataway, NJ: Camber Pharmaceuticals, Inc.; June 2021.
5. Lopinavir-ritonavir solution [package insert]. Philadelphia, PA: Lannett Company, Inc.; November 2020.
6. Norvir [package insert]. North Chicago, IL: AbbVie Inc.; December 2022.
7. Prezista [package insert]. Horsham, PA: Janssen Products, LP; March 2023.
8. Reyataz [package insert]. Princeton, NJ: Bristol-Myers Squibb Company; November 2023.
9. Ritonavir [package insert]. Warren, NJ: Cipla USA Inc.; March 2023.
10. Viracept [package insert]. New York, NY: Pfizer Inc.; October 2023.