This policy applies to the following:

✓	Standard Control (SF)		Managed Medicaid Template (MMT)		ACSF Chart (ACSFC)		Medical Benefit		Medicare Part B
✓	Standard Control – Choice (SCCF)		Marketplace (MF)		SF Chart (SFC)		Medical: Advanced Biosimilars First		Medicare Part B: Biosimilars First
	Preferred Drug Plan Design (PDPD)		Aetna Health Exchange (AHE)		VF Chart (VFC)		Medical Benefit: Managed Medicaid		Medicare Part B: Advanced Biosimilars First
	Advanced Control Specialty (ACSF)		IVL		New to Market (NTM)		Medical Benefit: Add-on		
	Advanced Control Specialty – Choice (ACSCF)		Value (VF)						

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EXCEPTIONS CRITERIA

HIV AGENTS- PROTEASE INHIBITORS

PREFERRED PRODUCTS: ATAZANAVIR, DARUNAVIR AND RITONAVIR

POLICY

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

I. PLAN DESIGN SUMMARY

This program applies to the HIV protease inhibitor products specified in this policy. Coverage for 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 and Reyataz powder for the first time. This program also applies to all members requesting treatment with Kaletra, Norvir, Prezista tablets and Reyataz capsules.

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

Table. Protease inhibitors

Preferred Products*	Targeted Products
• ritonavir (generic)	• **Norvir** (ritonavir)
• atazanavir (generic) • darunavir (generic)	• **Kaletra** (lopinavir-ritonavir) • **Lexiva** (fosamprenavir) • **Prezista** (darunavir) • **Reyataz** (atazanavir) • **Viracept** (nelfinavir)

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

II. EXCEPTION CRITERIA

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

Coverage for a targeted product is provided when any of the following criteria is met:

A. The request is for Norvir and either of the following is met:
   1. 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.

This policy applies to the following:

✓	Standard Control (SF)		Managed Medicaid Template (MMT)		ACSF Chart (ACSFC)		Medical Benefit		Medicare Part B
✓	Standard Control – Choice (SCCF)		Marketplace (MF)		SF Chart (SFC)		Medical: Advanced Biosimilars First		Medicare Part B: Biosimilars First
	Preferred Drug Plan Design (PDPD)		Aetna Health Exchange (AHE)		VF Chart (VFC)		Medical Benefit: Managed Medicaid		Medicare Part B: Advanced Biosimilars First
	Advanced Control Specialty (ACSF)		IVL		New to Market (NTM)		Medical Benefit: Add-on		
	Advanced Control Specialty – Choice (ACSCF)		Value (VF)						

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2. The requested product is Norvir powder packets and the member is unable to reliably swallow tablets.

B. The request is for Kaletra, Lexiva, or Viracept and any of the following is met:
   1. Member is less than 3 years of age.
   2. Member is 3 years of age to less than 6 years of age and the member weighs greater than 10 kg, and the member has a documented inadequate response, intolerable adverse event, or contraindication to darunavir.
   3. Member is at least 6 years of age and both of the following are met:
      a. Member weighs at least 15 kg.
      b. Member has a documented inadequate response, intolerable adverse event, or contraindication to atazanavir and darunavir.

C. The request is for Prezista and any of the following is met:
   1. Member is currently receiving treatment with Prezista suspension, excluding when Prezista suspension is obtained as samples or via manufacturer's patient assistance programs.
   2. Member is 3 years of age and less than 6 years of age, and the 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.
   3. Member is 6 years of age and older and all of the following are met:
      a. Member weighs at least 15 kg.
      b. 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.
      c. Member has a documented inadequate response, intolerable adverse event, or contraindication to atazanavir.

D. The request is for Reyataz and any of the following is met:
   1. Member is currently receiving treatment with Reyataz powder, excluding when Reyataz powder is obtained as samples or via manufacturer's patient assistance programs.
   2. Member is less than 3 years of age.
   3. Member is 3 years of age to less than 6 years of age and any of the following is met:
      a. Member weighs at least 10 kg.
      b. Member has a documented inadequate response, intolerable adverse event, or contraindication to darunavir.
   4. Member is 6 years of age and older and all of the following are met:
      a. Member weighs at least 15 kg.
      b. 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.
      c. Member has a documented inadequate response, intolerable adverse event, or contraindication to darunavir.

This policy applies to the following:

✓	Standard Control (SF)		Managed Medicaid Template (MMT)		ACSF Chart (ACSFC)		Medical Benefit		Medicare Part B
✓	Standard Control – Choice (SCCF)		Marketplace (MF)		SF Chart (SFC)		Medical: Advanced Biosimilars First		Medicare Part B: Biosimilars First
	Preferred Drug Plan Design (PDPD)		Aetna Health Exchange (AHE)		VF Chart (VFC)		Medical Benefit: Managed Medicaid		Medicare Part B: Advanced Biosimilars First
	Advanced Control Specialty (ACSF)		IVL		New to Market (NTM)		Medical Benefit: Add-on		
	Advanced Control Specialty – Choice (ACSCF)		Value (VF)						

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REFERENCES

1. Atazanavir [package insert]. East Windsor, NJ: Aurobindo Pharma USA, Inc.; February 2023.
2. Darunavir [package insert]. Baltimore, MD: Lupin Pharmaceuticals, Inc.; June 2023.
3. Kaletra [package insert]. North Chicago, IL: AbbVie Inc.; April 2023.
4. Lexiva [package insert]. Research Triangle Park, NC: ViiV Healthcare; October 2020.
5. Norvir [package insert]. North Chicago, IL: AbbVie Inc.; December 2022.
6. Prezista [package insert]. Horsham, PA: Janssen Products, LP; March 2023.
7. Reyataz [package insert]. Princeton, NJ: Bristol-Myers Squibb Company; September 2020.
8. Ritonavir [package insert]. Warren, NJ: Cipla USA Inc.; March 2023.
9. Viracept [package insert]. Research Triangle Park, NC: ViiV Healthcare; March 2021.