

This policy applies to the following:

	Standard Opt-in	PD/PD	Marketplace	Medical Benefit	Medicare Part B	Reference #
	Standard Opt-out	✓ ACSF	MMT	Medical Benefit: Biosimilars First	Medicare Part B: Biosimilars First	4736-D
	VF	✓ Balanced	Medical Benefit: Managed Medicaid	Medical Benefit: Add-on	Medicare Part B: Add-on	

EXCEPTIONS CRITERIA HIV AGENTS- PROTEASE INHIBITORS

PREFERRED PRODUCTS: ATAZANAVIR, LOPINAVIR-RITONAVIR SOLUTION, EVOTAZ, PREZCOBIX, PREZISTA

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 products specified in this policy. Coverage for targeted products is provided based on clinical circumstances that would exclude the use of the preferred product 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 all members requesting treatment with Lexiva and to members who are new to treatment with Invirase and Viracept for the first time.

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

Table. Protease inhibitors

	Product(s)
Preferred*	<ul style="list-style-type: none">atazanavirlopinavir-ritonavir solutionEvotaz (atazanavir and cobicistat)Prezcobix (darunavir and cobicistat)Prezista (darunavir)
Targeted	<ul style="list-style-type: none">Invirase (saquinavir)Lexiva (fosamprenavir)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. Member is currently receiving treatment with Invirase or Viracept, excluding when the requested targeted product is obtained as samples or via manufacturer's patient assistance programs.
- B. The request is for Invirase and the member has a documented inadequate response, intolerable adverse event, or contraindication to at least three of the preferred products.

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C. The request is for Lexiva and either of the following are met:

1. Member is less than 3 years of age and the member has a documented inadequate response, intolerable adverse event, or contraindication to lopinavir-ritonavir solution.
2. Member is 3 years of age to less than 6 years of age or the member weighs less than 15 kg and the member has a documented inadequate response, intolerable adverse event, or contraindication to both lopinavir-ritonavir solution and Prezista.
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 lopinavir-ritonavir solution, Prezista, and atazanavir.
4. Member is at least 6 years of age and both of the following are met:
 - a. Member weighs at least 35 kg.
 - b. Member has a documented inadequate response, intolerable adverse event, or contraindication to at least three of the following: lopinavir-ritonavir solution, Prezista, atazanavir, and Evotaz.
5. Member is at least 6 years of age and both of the following are met:
 - a. Member weighs at least 40 kg.
 - b. Member has a documented inadequate response, intolerable adverse event, or contraindication to at least 3 of the preferred products.

D. The request is for Viracept and any of the following are met:

1. Member is less than 3 years of age and the member has a documented inadequate response, intolerable adverse event, or contraindication to lopinavir-ritonavir solution.
2. Member is 3 years of age to less than 6 years of age or the member weighs less than 15 kg and the member has a documented inadequate response, intolerable adverse event, or contraindication to both lopinavir-ritonavir solution and Prezista.
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 lopinavir-ritonavir solution, Prezista, and atazanavir.
4. The member is at least 6 years of age and both of the following are met:
 - a. Member weighs at least 35 kg.
 - b. Member has a documented inadequate response, intolerable adverse event, or contraindication to at least three of the following: lopinavir-ritonavir solution, Prezista, atazanavir, and Evotaz.
5. The member is at least 6 years of age and both of the following are met:
 - a. Member weighs at least 40 kg.
 - b. Member has a documented inadequate response, intolerable adverse event, or contraindication to at least 3 of the preferred products.

REFERENCES

1. Atazanavir [package insert]. East Windsor, NJ: Aurobindo Pharma USA, Inc.; November 2020.
2. Lopinavir-ritonavir solution [package insert]. Philadelphia, PA: Lannett Company, Inc.; November 2020.
3. Evotaz [package insert]. Princeton, NJ: Bristol-Myers Squibb Company; July 2020.
4. Prezcobix [package insert]. Titusville, NJ: Janssen Therapeutics; December 2020.
5. Prezista [package insert]. Titusville, NJ: Janssen Therapeutics; December 2020.

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6. Invirase [package insert]. South San Francisco, CA: Genentech, Inc.; September 2020.
7. Lexiva [package insert]. Research Triangle Park, NC: ViiV Healthcare; March 2019.
8. Viracept [package insert]. Research Triangle Park, NC: ViiV Healthcare; March 2021.