

Clinical Policy: Infectious Disease Agents: Antivirals - HIV

Reference Number: OH.PHAR.PPA.73

Effective Date: 01.20

Last Review Date: 10.20

Line of Business: Medicaid

[Coding Implications](#)
[Revision Log](#)

See [Important Reminder](#) at the end of this policy for important regulatory and legal information.

Description:

See Appendix A for list of medications requiring prior authorization.

FDA Approved Indication(s):

For the treatment of human immunodeficiency virus (HIV) infection.

Policy/Criteria

Provider must submit documentation (such as office chart notes, lab results or other clinical information) supporting that member has met all approval criteria.

It is the policy of Buckeye Health Plan, an affiliate of Centene Corporation[®], that Crixivan, Invirase, Lexiva, Viracept, Aptivus, Symtuza, Videx, Epivir, Combivir, Zerit, Ziagen, Viread 250mg tablets and oral powder, Edurant, Intelence, Nevirapine IR, Nevirapine ER, Rescriptor, Selzentry, Fuzeon, Stribild, and Tybost are **medically necessary** when the following criteria are met:

I. Initial Approval Criteria

A. For Crixivan, Invirase, Lexiva, Viracept, Aptivus, Symtuza, Videx, Epivir, Combivir, Zerit, Ziagen, Viread 250mg tablets & oral powder, Edurant, Intelence, Nevirapine IR, Nevirapine ER, Rescriptor, Selzentry, and Tybost (must meet all):

1. Diagnosis of HIV-1 infection;
2. Member must meet labeled age requirements for the medication;
3. Documentation that there has been a therapeutic failure to no less than a 30 day trial of at least one medication not requiring prior approval UNLESS there is a reason the member cannot be changed to a preferred medication. Acceptable reasons include:
 - Allergies to all medications not requiring prior approval.
 - Contraindication to or drug-to-drug interaction with medications not requiring prior approval.
 - History of unacceptable/toxic side effects to meds not requiring prior approval.
4. For Symtuza: Request must document clinical justification for the member's inability to use the individual components (Prezcobix and Descovy).

****NOTE – Grandfathering:** Members who have a claim for a non-preferred drug in the previous 120 days will be automatically approved to continue the drug through the automated PA system. Members who have taken the drug in the previous 120 days, but do not have claims history (e.g. new to Medicaid), will be approved for PA after prescriber contact.

Approval duration: 12 months.

B. For Stribild (must meet all):

1. Diagnosis of HIV-1 infection;
2. Age ? 18 years OR children and adolescents 12 to 17 years weighing 35 kg or more;
3. Prescribed as monotherapy for HIV-1 infection;
4. Member is treatment naïve OR stable on an antiretroviral regimen for at least 6 months and is virologically suppressed (current HIV-1 RNA <50 copies/mL);
5. Submission of resistance test (dated within the past 3 months) demonstrating virologic susceptibility to **ALL** of the following components of Stribild: elvitegravir, emtricitabine, and tenofovir;
6. Documentation that there has been a therapeutic failure to no less than a 30 day trial of at least one medication not requiring prior approval and within the same class UNLESS there is a reason the member cannot be changed to a preferred medication. Acceptable reasons include:
 - Allergies to all medications not requiring prior approval.
 - Contraindication to or drug-to-drug interaction with medications not requiring prior approval.
 - History of unacceptable/toxic side effects to medications not requiring prior approval.

****NOTE – Grandfathering:** Members who have a claim for a non-preferred drug in the previous 120 days will be automatically approved to continue the drug through the automated PA system. Members who have taken the drug in the previous 120 days, but do not have claims history (e.g. new to Medicaid), will be approved for PA after prescriber contact.

Approval duration: 12 months.

C. For Fuzeon (must meet all):

1. Diagnosis of HIV-1 infection;
2. Age ? 6 years;
3. Fuzeon is prescribed concurrently with additional antiretroviral agents to which member is susceptible;
4. Documentation that there has been a therapeutic failure to no less than a 30 day trial of at least one medication not requiring prior approval UNLESS there is a reason the member cannot be changed to a preferred medication. Acceptable reasons include:
 - Allergies to all medications not requiring prior approval.
 - Contraindication to or drug-to-drug interaction with medications not requiring prior approval.
 - History of unacceptable/toxic side effects to medications not requiring prior approval.

****NOTE – Grandfathering:** Members who have a claim for a non-preferred drug in the previous 120 days will be automatically approved to continue the drug through the automated PA system. Members who have taken the drug in the previous 120 days, but do not have claims history (e.g. new to Medicaid), will be approved for PA after prescriber contact.

Approval duration: 12 months.

D. Other diagnoses/indications:

1. There are no pharmacy and therapeutic committee approved off-label use criteria for the diagnosis;
2. Use is supported by one of the following (a, b, or c):
 - a. The National Comprehensive Cancer Network (NCCN) Drug Information and Biologics Compendium level of evidence 1 or 2A;
 - b. Evidence from at least two high-quality, published studies in reputable peer-reviewed journals or evidence-based clinical practice guidelines that provide all of the following (i – iv):
 - i. Adequate representation of the member’s clinical characteristics, age, and diagnosis;
 - ii. Adequate representation of the prescribed drug regimen;
 - iii. Clinically meaningful outcomes as a result of the drug therapy in question;
 - iv. Appropriate experimental design and method to address research questions;
 - c. Micromedex DrugDex[®] with strength of recommendation Class I, IIa, or IIb;
3. Prescribed by or in consultation with an appropriate specialist for the diagnosis;
4. Failure of an adequate trial of at least two FDA-approved drugs for the indication and/or drugs that are considered the standard of care, when such agents exist for the same indication at maximum indicated doses, unless no such drugs exist, at maximum indicated doses, unless contraindicated or clinically significant adverse effect are experienced;
5. Dosing regimen and duration are within dosing guidelines recommended by clinical practice guidelines and/or medical literature.

Approval duration: 12 months.

II. Diagnoses/Indications for which coverage is NOT authorized:

Non-FDA approved indications, which are not addressed in this policy, unless there is sufficient documentation of efficacy and safety according to the off label use policy – CP.PMN.53 for Medicaid or evidence of coverage documents.

III. Appendices/General Information

Appendix A: Medications requiring prior authorization

HIV PROTEASE INHIBITORS AND COMBINATIONS

NO PA REQUIRED “PREFERRED”	PA REQUIRED “NON-PREFERRED”
EVOTAZ [®] (atazanavir/cobicistat)	CRIXIVAN [®] (indinavir sulfate)
KALETRA [®] (lopinavir/ritonavir)	INVIRASE [®] (saquinavir mesylate)
ATAZANAVIR SULFATE capsules, oral powder (generic of Reyatez [®])	LEXIVA [®] (fosamprenavir calcium)
	VIRACEPT [®] (nelfinavir mesylate)

HIV NON-PEPTIDIC PROTEASE INHIBITORS AND COMBINATIONS

NO PA REQUIRED "PREFERRED"	PA REQUIRED "NON-PREFERRED"
PREZCOBIX® (darunavir/cobicistat) PREZISTA® (darunavir ethanolate)	APTIVUS® (tipranavir; tipranavir/vitamin E) SYM TUZATM (darunavir, cobicistat, emtricitabine, tenofovir alafenamide) †

† Request must address use of the individual components PREZCOBIX and DESCOVY

HIV REVERSE TRANSCRIPTASE INHIBITORS, NUCLEOSIDE ANALOGS AND COMBINATIONS

NO PA REQUIRED "PREFERRED"	PA REQUIRED "NON-PREFERRED"
ABACAVIR SULFATE tablet (generic of Ziagen®) ABACAVIR/LAMIVUDINE (generic of Epzicom®) EMTRIVA® (emtricitabine) ABACAVIR/LAMIVUDINE/ZIDOVUDINE (generic TRIZIVIR®) ZIDOVUDINE (generic of Retrovir®)	DIDANOSINE capsule (generic of Videx®) LAMIVUDINE solution, tablet (generic of Epivir®) LAMIVUDINE/ZIDOVUDINE (generic of Combivir®) STAVUDINE (generic of Zerit®) VIDEX® solution (didanosine) ZIAGEN® solution (abacavir sulfate)

HIV REVERSE TRANSCRIPTASE INHIBITORS, NUCLEOTIDE ANALOGS

NO PA REQUIRED "PREFERRED"	PA REQUIRED "NON-PREFERRED"
VIREAD® 150 mg (tenofovir disoproxil fumarate) TENOFOVIR DISOPROXIL 300mg (generic for VIREAD®)	VIREAD® 250mg & Oral Powder (tenofovir disoproxil fumarate)

HIV REVERSE TRANSCRIPTASE INHIBITORS, NON-NUCLEOSIDE ANALOGS

NO PA REQUIRED "PREFERRED"	PA REQUIRED "NON-PREFERRED"
EFAVIRENZ (generic for SUSTIVA®) PIFELTRO™ (doravirine)	EDURANT® (rilpivirine) INTELENCE® (etravirine) NEVIRAPINE ER (generic of Viramune® XR) NEVIRAPINE IR (generic of Viramune®) RESCRIPTOR® (delavirdine mesylate)

HIV INTEGRASE STRAND TRANSFER INHIBITORS

NO PA REQUIRED "PREFERRED"	PA REQUIRED "NON-PREFERRED"
ISENTRESS® tablets, chewable tablet, powder packets (raltegravir potassium) TIVICAY®, TIVICAY® PD (dolutegravir sodium)	

HIV CCR5 CO-RECEPTOR ANTAGONISTS

NO PA REQUIRED "PREFERRED"	PA REQUIRED "NON-PREFERRED"
	SELZENTRY® (maraviroc)

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HIV FUSION INHIBITORS

NO PA REQUIRED "PREFERRED"	PA REQUIRED "NON-PREFERRED"
	FUZEON® (enfuvirtide)

HIV RTI, NUCLEOSIDE-NUCLEOTIDE ANALOGS

NO PA REQUIRED "PREFERRED"	PA REQUIRED "NON-PREFERRED"
DESCOVY® (emtricitabine/ tenofovir alafenamide) CIMDUOTM (lamivudine/tenofovir) TRUVADA® (emtricitabine/tenofovir)	

HIV RTI, NUCLEOSIDE-NUCLEOTIDE ANALOGS AND COMBINATIONS

NO PA REQUIRED "PREFERRED"	PA REQUIRED "NON-PREFERRED"
DELSTRIGOTM (doravirine, lamivudine, and tenofovir disoproxil) SYMFI & SYMFI LOTM (efavirenz/lamivudine/tenofovir)	

HIV RTI, NUCLEOSIDE, NUCLEOTIDE, & NON-NUCLEOSIDE ANALOGS

NO PA REQUIRED "PREFERRED"	PA REQUIRED "NON-PREFERRED"
ATRIPLA® (emtricitabine/efavirenz/tenofovir) COMPLERA® (emtricitabine/rilpivirine/tenofovir) ODEFSEY® (emtricitabine/rilpivirine/tenofovir alafenamide)	

HIV INTEGRASE INHIBITOR & RTI COMBINATION

NO PA REQUIRED "PREFERRED"	PA REQUIRED "NON-PREFERRED"
DOVATO (dolutegravir/lamivudine) + GENVOYA® (elvitegravir, cobicistat, emtricitabine, and tenofovir alafenamide) TRIUMEQ® (dolutegravir/abacavir/lamivudine) [†]	STRIBILD® (elvitegravir/cobicistat/emtricitabine/tenofovir)

[†] Request must address use of the individual components TIVICAY and EPZICOM.

HIV INTEGRASE INHIBITOR & NUCLEOSIDE ANALOG COMBINATIONS

NO PA REQUIRED "PREFERRED"	PA REQUIRED "NON-PREFERRED"
BIKTARVY® (bictegravir/emtricitabine/tenofovir)	

HIV INTEGRASE INHIBITOR & NON-NUCLEOSIDE COMBINATION

NO PA REQUIRED "PREFERRED"	PA REQUIRED "NON-PREFERRED"
JULUCA (dolutegravir/rilpivirine)	

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HIV PHARMACOKINETIC ENHANCERS (CYP3A INHIBITORS)

NO PA REQUIRED "PREFERRED"	PA REQUIRED "NON-PREFERRED"
RITONAVIR (generic for Norvir®) NORVIR® oral Solution (ritonavir) NORVIR® oral Powder (ritonavir)	TYBOST® (cobicistat)

Appendix B: Abbreviation/Acronym Key

CCR5: C-C chemokine receptor type 5

CYP3A: Cytochrome P4503A

ER: Extended Release

FDA: Food and Drug Administration

HIV: Human Immunodeficiency Virus

IR: Immediate Release

PA: Prior Authorization

RNA: Ribonucleic Acid

Appendix C: Therapeutic Alternatives

This table provides a listing of preferred alternative therapy recommended in the approval criteria. The drugs listed here may not be a formulary agent for all relevant lines of business and may require prior authorization.

Drug Name	Dosing Regimen	Dose Limit/ Maximum Dose
EVOTAZ® (atazanavir/cobicistat)	1 tablet once daily	300 mg/150 mg daily
KALETRA® (lopinavir/ritonavir)	400 mg/100 mg twice daily	800 mg/200 mg per day
REYATAZ® capsules, oral powder (atazanavir sulfate)	300 mg w/ ritonavir 100 mg daily; alternatively 400 mg daily if unable to tolerate ritonavir	300 mg/day w/ ritonavir & 400 mg/day without ritonavir
PREZCOBIX® (darunavir/cobicistat)	1 tablet once daily	800 mg/150 mg daily
PREZISTA® (darunavir ethanolate)	Treatment-naïve or treatment-experienced w/ no darunavir resistance: 800 mg daily w/ ritonavir 100 mg daily Treatment-experienced w/ at least one darunavir resistance: 600 mg twice daily w/ ritonavir 100 mg twice daily	1200 mg/day

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Drug Name	Dosing Regimen	Dose Limit/ Maximum Dose
ABACAVIR SULFATE tablet (generic of Ziagen®)	300 mg twice daily or 600 mg once daily	600 mg/day
ABACAVIR/LAMIVUDINE (generic of Epzicom®)	1 tablet once daily	Abacavir 600 mg/day; lamivudine 300 mg/day
EMTRIVA® (emtricitabine)	Capsules: 200 mg once daily Oral solution: 240 mg once daily	200 mg/day for capsules; 240 mg/day for oral solution
ABACAVIR/LAMIVUDINE/ZIDOVUDINE (generic TRIZIVIR®)	1 tablet twice daily	Abacavir 600 mg/day; lamivudine 300 mg/day; zidovudine 600 mg/day
ZIDOVUDINE (generic of Retrovir®)	300 mg twice daily or 200 mg three times daily	600 mg/day
VIREAD® 150 mg (tenofovir disoproxil fumarate)	1 tablet once daily	300 mg/day
TENOFIVIR DISOPROXIL 300mg (generic for VIREAD®)	1 tablet once daily	300 mg/day
EFAVIRENZ (generic for SUSTIVA®)	600 mg once daily at bedtime	600 mg/day
PIFELTRO™ (doravirine)	No concurrent treatment with rifabutin: 1 tablet once daily Concurrent treatment with rifabutin: 1 tablet every 12 hours for the duration of rifabutin concurrent therapy	100 mg/day; 200 mg/day if given with rifabutin
ISENTRESS® tablets, chewable tablet, powder packets (raltegravir potassium)	400 mg tablet: 400 mg twice daily. During coadministration with rifampin, the recommended dosage is 800 mg twice daily 600 mg tablet: 1,200 mg once daily	800 mg/day for the 400 mg film-coated tablet; 1,600 mg/day with concomitant rifampin; 1,200 mg/day for the 600 mg film-coated tablet

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Drug Name	Dosing Regimen	Dose Limit/ Maximum Dose
TIVICAY® (dolutegravir sodium)	<p>Treatment-naive or treatment-experienced but integrase strand transfer inhibitor naive: 50 mg once daily</p> <p>Coadministration w/ efavirenz, fosamprenavir & ritonavir, tipranavir & ritonavir, carbamazepine, or rifampin: 50 mg twice daily</p>	100 mg/day
DESCOVY® (emtricitabine/ tenofovir alafenamide)	1 tablet once daily	1 tablet/day
CIMDUO™ (lamivudine/tenofovir)	1 tablet once daily	1 tablet/day
TRUVADA® (emtricitabine/tenofovir)	1 tablet once daily	200 mg/day emtricitabine and 300 mg/day tenofovir DF
DELSTRIGO™ (doravirine, lamivudine, and tenofovir disoproxil)	<p>No concurrent treatment with rifabutin: 1 tablet once daily</p> <p>Concurrent treatment w/ rifabutin: 1 tablet (doravirine 100 mg; lamivudine 300 mg; tenofovir disoproxil fumarate 300 mg) daily. 12 hours later give additional 100 mg of doravirine each day</p>	<p>Doravirine 100 mg/day; lamivudine 300 mg/day; tenofovir disoproxil fumarate 300 mg/day. If given with rifabutin, doravirine 200 mg/day; lamivudine 300 mg/day; tenofovir disoproxil fumarate 300 mg/day</p>
SYMFI & SYMFI LO™ (efavirenz/lamivudine/tenofovir)	<p>Symfi: 1 tablet once daily at bedtime</p> <p>Symfi Lo: 1 tablet once daily at bedtime</p>	<p>Efavirenz 600 mg/day; lamivudine 300 mg/day; tenofovir DF 300 mg/day</p> <p>Efavirenz 400 mg/day; lamivudine 300mg/day; tenofovir DF 300 mg/day</p>

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Drug Name	Dosing Regimen	Dose Limit/ Maximum Dose
ATRIPLA® (emtricitabine/efavirenz/tenofovir)	1 tablet once daily at bedtime	1 tablet/day
COMPLERA® (emtricitabine/rilpivirine/tenofovir)	1 tablet once daily	1 tablet/day
ODEFSEY® (emtricitabine/rilpivirine/tenofovir alafenamide)	1 tablet once daily	1 tablet/day
DOVATO (dolutegravir/lamivudine)	Treatment-naïve: 1 tablet (50 mg dolutegravir; 300 mg lamivudine) daily Coadministration with carbamazepine or rifampin: 1 tablet (50 mg dolutegravir; 300 mg lamivudine) daily. 12 hours later give additional 50 mg of dolutegravir	1 tablet/day (dolutegravir 50 mg/day; lamivudine 300 mg/day); dolutegravir 100 mg/day when coadministered with certain drugs
GENVOYA® (elvitegravir, cobicistat, emtricitabine, and tenofovir alafenamide)	1 tablet once daily	1 tablet/day
TRIUMEQ® (dolutegravir/abacavir/lamivudine)	1 tablet (600 mg abacavir; 50 mg dolutegravir; 300 mg lamivudine) once daily Coadministration with efavirenz, fosamprenavir/ritonavir, tipranavir/ritonavir, carbamazepine, or rifampin: 1 tablet (600 mg abacavir; 50 mg dolutegravir; 300 mg lamivudine) daily. 12 hours later give additional 50 mg of dolutegravir	1 tablet/day (abacavir 600 mg/day; dolutegravir 50 mg/day; lamivudine 300 mg/day); dolutegravir 100 mg/day when coadministered with certain drugs
BIKTARVY® (bictegravir/emtricitabine/tenofovir)	1 tablet once daily	1 tablet/day

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Drug Name	Dosing Regimen	Dose Limit/ Maximum Dose
JULUCA (dolutegravir/rilpivirine)	No concurrent treatment with rifabutin: 1 tablet once daily Concurrent treatment w/ rifabutin: 1 tablet (dolutegravir 50 mg; rilpivirine 25 mg) plus an additional 25 mg tablet of rilpivirine (total daily rilpivirine dose of 50 mg) once daily	dolutegravir 50 mg/day; rilpivirine 25 mg/day; rilpivirine 50 mg/day when administered with rifabutin
RITONAVIR (generic for Norvir®)	600 mg twice daily	1200 mg/day
NORVIR® oral Solution (ritonavir)	600 mg twice daily	1200 mg/day
NORVIR® oral Powder (ritonavir)	600 mg every 12 hours	1200 mg/day

Therapeutic alternatives are listed as Brand name® (generic) when the drug is available by brand name only and generic (Brand name®) when the drug is available by both brand and generic.

Appendix D: Contraindications/Boxed Warnings

- Contraindication(s):
 - [AV Block](#)
 - [Hepatic Disease](#)
 - [Hypokalemia](#)
 - [Hypomagnesemia](#)
 - [QT Prolongation](#)
 - [Torsade de Pointes](#)
- Boxed warning(s):
 - Bone Marrow Suppression
 - Hepatitis B Exacerbation
 - Hepatotoxicity
 - Intracranial Bleeding
 - Myopathy

IV. Dosage and Administration

- Varies by drug product. See FDA approved dosing and administration AND Appendix C.

V. Product Availability

Drug Name	Availability
Abacavir	Oral solution: 20 mg/mL

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Drug Name	Availability
Abacavir	Tablets: 300 mg
Abacavir/Lamivudine	Tablets: 600 mg-300 mg
Abacavir/Lamivudine/Zidovudine	Tablets: 300 mg-150 mg-300 mg
Aptivus	Capsules: 250 mg
Aptivus	Oral solution: 100 mg/mL
Atazanavir	Capsules: 150 mg, 200 mg, 300 mg
Atripla	Tablets: 600 mg-200 mg-300 mg
Biktarvy	Tablets: 50 mg-200 mg-25 mg
Cimduo	Tablets: 300 mg-300 mg
Complera	Tablets: 200 mg-25 mg-300 mg
Crixivan	Capsules: 200 mg, 400 mg
Delstrigo	Tablets: 100 mg-300 mg-300 mg
Descovy	Tablets: 200 mg-25 mg
Didanosine	Capsules: 125 mg, 200 mg, 250 mg, 400 mg
Dovato	Tablets: 50 mg-300 mg
Edurant	Tablets: 25 mg
Efavirenz	Capsules: 50 mg, 200 mg
Efavirenz	Tablets: 600 mg
Emtriva	Capsules: 200 mg
Emtriva	Oral solution: 10 mg/mL
Evotaz	Tablets: 300 mg-150 mg
Fosamprenavir Calcium	Tablets: 700 mg
Fuzeon	Solution for injection: 90 mg
Genvoya	Tablets: 150 mg-150 mg-200 mg-10 mg
Intelence	Tablets: 25 mg, 100 mg, 200 mg
Invirase	Tablets: 500 mg
Isentress	Chewable Tablets: 25 mg, 100 mg
Isentress	Granules for suspension: 100 mg
Isentress	Tablets: 400 mg
Isentress HD	Tablets: 600 mg
Juluca	Tablets: 50 mg-25 mg
Kaletra	Tablets: 100 mg-25 mg, 200 mg-50 mg
Lamivudine	Oral solution: 10 mg/mL
Lamivudine	Tablets: 150 mg, 300 mg
Lamivudine/Zidovudine	Tablets: 150 mg-300 mg
Lexiva	Oral suspension: 50 mg/mL
Lopinavir/Ritonavir	Oral solution: 80 mg-20 mg/mL
Nevirapine	Oral suspension: 50 mg/5 mL
Nevirapine IR	Tablets: 200 mg
Nevirapine ER	Tablets: 100 mg, 400 mg
Norvir	Capsules: 100 mg
Norvir	Oral powder: 100 mg
Norvir	Oral solution: 80 mg/mL
Odefsey	Tablets: 200 mg-25 mg-25 mg

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Drug Name	Availability
Pifeltro	Tablets: 100 mg
Prezcobix	Tablets: 800 mg-150 mg
Prezista	Oral suspension: 100 mg/mL
Prezista	Tablets: 75 mg, 150 mg, 600 mg, 800 mg
Rescriptor	Tablets: 200 mg
Retrovir	Solution for injection: 10 mg/mL
Reyataz	Oral powder: 50 mg
Ritonavir	Tablets: 100 mg
Selzentry	Oral solution: 20 mg/mL
Selzentry	Tablets: 25 mg, 75 mg, 150 mg, 300 mg
Stavudine	Oral powder: 1 mg/mL
Stavudine	Capsules: 15 mg, 20 mg, 30 mg, 40 mg
Stribild	Tablets: 150 mg-150 mg-200 mg-300 mg
Symfi	Tablets: 600 mg-300 mg-300 mg
Symfi Lo	Tablets: 400 mg-300 mg-300 mg
Symtuza	Tablets: 800 mg-150 mg-200 mg-10 mg
Tenofovir Disoproxil Fumarate	Tablets: 300 mg
Tivicay	Tablets: 10 mg, 25 mg, 50 mg
Triumeq	Tablets: 600 mg-50 mg-300 mg
Truvada	Tablets: 100 mg-150 mg, 133 mg-200 mg, 167 mg-250 mg, 200 mg-300 mg
Tybost	Tablets: 150 mg
Videx	Oral powder: 2 g
Viracept	Oral suspension: 50 mg/g
Viracept	Tablets: 250 mg, 625 mg
Viread	Oral powder: 40 mg/scoop
Viread	Tablets: 150 mg, 200 mg, 250 mg, 300 mg
Zidovudine	Capsules: 100 mg
Zidovudine	Oral solution: 50 mg/5 mL
Zidovudine	Tablets: 300 mg

VI. References

- Abacavir. Clinical Pharmacology. Elsevier. Tampa, FL. Available at <https://www.clinicalpharmacology-ip.com>. Accessed November 12, 2019.
- Efavirenz. Clinical Pharmacology. Elsevier. Tampa, FL. Available at <https://www.clinicalpharmacology-ip.com>. Accessed November 12, 2019.
- Efavirenz/Emtricitabine/Tenofovir. Clinical Pharmacology. Elsevier. Tampa, FL. Available at <https://www.clinicalpharmacology-ip.com>. Accessed November 12, 2019.
- Fuzeon (enfuvirtide) [package insert]. San Francisco, CA; Genentech Inc.; Revised 12/2018.
- Lamivudine. Clinical Pharmacology. Elsevier. Tampa, FL. Available at <https://www.clinicalpharmacology-ip.com>. Accessed November 12, 2019.
- Stribild (elvitegravir/cobicistat/emtricitabine/tenofovir disoproxil fumarate) [package insert]. Foster City, CA; Gilead Sciences Inc.; Revised 01/2019.

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Reviews, Revisions, and Approvals	Date	P&T Approval Date
New policy created.	10.19	N/A
Added generic Reyataz to no PA required, preferred list; added Tivicay PD to no PA required, preferred list	10.20	N/A

Important Reminder

This clinical policy has been developed by appropriately experienced and licensed health care professionals based on a review and consideration of currently available generally accepted standards of medical practice; peer-reviewed medical literature; government agency/program approval status; evidence-based guidelines and positions of leading national health professional organizations; views of physicians practicing in relevant clinical areas affected by this clinical policy; and other available clinical information. The Health Plan makes no representations and accepts no liability with respect to the content of any external information used or relied upon in developing this clinical policy. This clinical policy is consistent with standards of medical practice current at the time that this clinical policy was approved. “Health Plan” means a health plan that has adopted this clinical policy and that is operated or administered, in whole or in part, by Centene Management Company, LLC, or any of such health plan’s affiliates, as applicable.

The purpose of this clinical policy is to provide a guide to medical necessity, which is a component of the guidelines used to assist in making coverage decisions and administering benefits. It does not constitute a contract or guarantee regarding payment or results. Coverage decisions and the administration of benefits are subject to all terms, conditions, exclusions and limitations of the coverage documents (e.g., evidence of coverage, certificate of coverage, policy, contract of insurance, etc.), as well as to state and federal requirements and applicable Health Plan-level administrative policies and procedures.

This clinical policy is effective as of the date determined by the Health Plan. The date of posting may not be the effective date of this clinical policy. This clinical policy may be subject to applicable legal and regulatory requirements relating to provider notification. If there is a discrepancy between the effective date of this clinical policy and any applicable legal or regulatory requirement, the requirements of law and regulation shall govern. The Health Plan retains the right to change, amend or withdraw this clinical policy, and additional clinical policies may be developed and adopted as needed, at any time.

This clinical policy does not constitute medical advice, medical treatment or medical care. It is not intended to dictate to providers how to practice medicine. Providers are expected to exercise professional medical judgment in providing the most appropriate care, and are solely responsible for the medical advice and treatment of members. This clinical policy is not intended to recommend treatment for members. Members should consult with their treating physician in connection with diagnosis and treatment decisions.

Providers referred to in this clinical policy are independent contractors who exercise independent judgment and over whom the Health Plan has no control or right of control. Providers are not agents or employees of the Health Plan.

This clinical policy is the property of the Health Plan. Unauthorized copying, use, and distribution of this clinical policy or any information contained herein are strictly prohibited. Providers, members and their representatives are bound to the terms and conditions expressed herein through the terms of their contracts. Where no such contract exists, providers, members and their representatives agree to be bound by such terms and conditions by providing services to members and/or submitting claims for payment for such services.

Note:

For Medicaid members, when state Medicaid coverage provisions conflict with the coverage provisions in this clinical policy, state Medicaid coverage provisions take precedence. Please refer to the state Medicaid manual for any coverage provisions pertaining to this clinical policy.

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