

Clinical Policy: Step Therapy

Reference Number: CP.PST.01

Effective Date: 12.28.17

Last Review Date: 02.20

Line of Business: Medicaid*

[Revision Log](#)

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

Description

This policy provides a list of drugs that require step therapy for drugs on the Preferred Drug List (PDL).

**This step therapy policy does not apply to drugs that are not on the Medicaid Health Plan's PDL. For non-formulary drugs, refer to the formulary exception policy, CP.PMN.16 Request for Medically Necessary Drug not on the PDL.*

FDA Approved Indication(s)

Various.

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 health plans affiliated with Centene Corporation[®] that the drugs identified within this policy are **medically necessary** when the following criteria are met:

I. Initial Approval Criteria

A. Electronic Step Therapy:

Drugs listed in the table below may be approved for the length of benefit for members who have had a previous trial of or who have contraindications to required step-through agents, when the request does not exceed the maximum indicated dose and stated quantity limit.

Drug Name	Required Step-Through Agents	Maximum Dose (Quantity Limit)
amlodipine/olmesartan (Azor [®])	Losartan or irbesartan	10/40 mg daily (1 tablet/day)
amlodipine/valsartan (Exforge [®])	Losartan or irbesartan	10/320 mg daily (1 tablet/day)
amlodipine/valsartan/HCTZ (Exforge HCT [®])	Losartan or irbesartan	10/320/25 mg daily (1 tablet/day)
darunavir, cobicistat, emtricitabine, tenofovir alafenamide (Symtuza [™])	If treatment naïve: Symfi [™] or Symfi Lo [™] (efavirenz/lamivudine/tenofovir disoproxil fumarate)	800/150/200/10 mg daily (1 tablet/day)

Drug Name	Required Step-Through Agents	Maximum Dose (Quantity Limit)
	If treatment experienced: any HIV antiretroviral agent	
doravirine, lamivudine, tenofovir disoproxil fumarate (Delstrigo™)	If treatment naïve: Symfi or Symfi Lo (efavirenz/lamivudine/tenofovir disoproxil fumarate) If treatment experienced: any HIV antiretroviral agent	100/300/300 mg daily (1 tablet/day)
efavirenz/emtricitabine/tenofovir disoproxil fumarate (Atripla®)	If treatment naïve: Symfi or Symfi Lo (efavirenz/lamivudine/tenofovir disoproxil fumarate) If treatment experienced: any HIV antiretroviral agent	600/200/300 mg daily (1 tablet/day)
emtricitabine/rilpivirine/tenofovir alafenamide (Odefsey®)	If treatment naïve: Symfi or Symfi Lo (efavirenz/lamivudine/tenofovir disoproxil fumarate) If treatment experienced: any HIV antiretroviral agent	200/25/25 mg daily (1 tablet/day)
emtricitabine/rilpivirine/tenofovir disoproxil fumarate (Complera®)	If treatment naïve: Symfi or Symfi Lo (efavirenz/lamivudine/tenofovir disoproxil fumarate) If treatment experienced: any HIV antiretroviral agent	200/25/300 mg daily (1 tablet/day)
ertugliflozin (Steglatro™)	90 days of metformin in the last 365 days or if current (within the last 3 months) HbA1c is $\geq 8.5\%$	15 mg/day (1 tablet/day)
ertugliflozin/metformin (Segluromet™)	90 days of metformin in the last 365 days or if current (within the last 3 months) HbA1c is $\geq 8.5\%$	15/2000 mg daily (2 tablets/day)
exemestane (Aromasin®)	One PDL aromatase inhibitor (e.g., anastrozole)	25 mg/day (1 tablet/day)
ezetimibe (Zetia®)	One of the following (a or b)	10 mg/day (1 tablet/day)

Drug Name	Required Step-Through Agents	Maximum Dose (Quantity Limit)
	<ul style="list-style-type: none"> a) Currently receiving ezetimibe or ezetimibe-simvastatin b) Prior use of at least one of the following statins: atorvastatin calcium, fluvastatin sodium, lovastatin, pitavastatin calcium, rosuvastatin calcium, pravastatin sodium, simvastatin, niacin-simvastatin, amlodipine besylate-atorvastatin calcium 	
ezetimibe/simvastatin (Vytorin [®])	One of the following (a or b) <ul style="list-style-type: none"> a) Currently receiving ezetimibe or ezetimibe-simvastatin b) Prior use of at least one of the following statins: atorvastatin calcium, fluvastatin sodium, lovastatin, pitavastatin calcium, rosuvastatin calcium, pravastatin sodium, simvastatin, niacin-simvastatin, amlodipine besylate-atorvastatin calcium 	10/40 mg/day for most patients 10/80 mg/day for patients already taking simvastatin 80 mg/day chronically without evidence of myopathy
fluticasone/vilanterol (Breo Ellipta [®])	fluticasone/salmeterol (generic Advair Diskus [®]) or budesonide/formoterol (generic Symbicort [®])	Asthma: 1 inhalation of 200 mcg fluticasone/25 mcg vilanterol per day (60 blisters every 30 days) COPD: 1 inhalation of 100 mcg fluticasone/25 mcg vilanterol per day (60 blisters every 30 days)
HCTZ/olmesartan (Benicar HCT [®])	Losartan or irbesartan	40/25 mg daily (1 tablet/day)
lamotrigine (Lamictal [®] XR [™])	Lamotrigine IR	Varies

Drug Name	Required Step-Through Agents	Maximum Dose (Quantity Limit)
levetiracetam (Keppra XR™)	Levetiracetam IR	3000 mg daily (4 tablet/day)
loodoxamide (Alomide®)	Two PDL anti-allergy ophthalmic agents	8 drops/eye/day
mometasone/formoterol (Dulera®)	fluticasone/salmeterol (generic Advair Diskus®) or budesonide/formoterol (generic Symbicort®)	Age 5 to 11 years: 4 inhalations of 50 mcg mometasone/5 mcg formoterol per day (1 inhaler every 30 days); Age ≥ 12 years: 4 inhalations of 200 mcg mometasone/5 mcg formoterol per day (1 inhaler every 30 days)
nedocromil (Alocril®)	Two PDL anti-allergy ophthalmic agents	8 drops/eye/day
olmesartan (Benicar®)	Losartan or irbesartan	40 mg daily (1 tablet/day)
olmesartan/amlodipine/HCTZ (Tribenzor®)	Losartan or irbesartan	40/10/25 mg daily (1 tablet/day)
rosuvastatin (Crestor®)	Atorvastatin or simvastatin	40 mg/day (1 tablet/day)
mesalamine (Apriso™, Asacol® HD, Lialda®, Pentasa®, and Delzicol®)	Generic preferred 5-aminosalicylate (e.g., mesalamine, sulfasalazine, balsalazide)	Varies

Approval duration: Length of Benefit

II. Continued Therapy

A. Step Therapy (must meet all):

1. Member meets one of the following (a or b):
 - a. Currently receiving medication via Centene benefit or member has previously met initial approval criteria;
 - b. Documentation supports that member is currently receiving Atripla, Complera, Delstrigo, Odefsey, or Symtuza for HIV infection and has received this medication for at least 30 days;
2. Dose does not exceeded the FDA-approved maximum recommended dose for the relevant drug.

Approval duration: Length of Benefit

III. Appendices/General Information

Appendix A: Abbreviation/Acronym Key

FDA: Food and Drug Administration

HbA1c: glycated hemoglobin

HCTZ: hydrochlorothiazide

HIV: human immunodeficiency virus

IR: immediate release

PDL: preferred drug list

Appendix B: Therapeutic Alternatives

Refer to required step-through drug(s) above.

Appendix C: Contraindications/Boxed Warnings

Refer to the package inserts for each of the drugs requiring step therapy.

IV. Dosage and Administration

Refer to the step therapy table in Section I.

V. Product Availability

Drug Name	Availability
amlodipine/olmesartan (Azor)	Tablets 5/20 mg, 10/20 mg, 5/40 mg, 10/40 mg
amlodipine/valsartan (Exforge)	Tablets: 5/160 mg, 10/160 mg, 5/320 mg, 10/320 mg
amlodipine/valsartan/ HCTZ (Exforge HCT)	Tablets: 5/160/12.5 mg, 10/160/12.5 mg, 5/160/25 mg, 10/160/25 mg, 10/320/25 mg
budesonide/formoterol (Symbicort)	Metered dose inhaler with inhalation aerosol containing budesonide/formoterol: 80/4.5 mcg, 160/4.5 mcg
darunavir, cobicistat, emtricitabine, tenofovir alafenamide (Symtuza)	Tablets: 800/150/200/10 mg
doravirine, lamivudine, tenofovir disoproxil fumarate (Delstrigo)	Tablets: 100/300/300 mg
efavirenz/emtricitabine/tenofovir disoproxil fumarate (Atripla)	Tablets: 600/200/300 mg
emtricitabine/rilpivirine/tenofovir alafenamide (Odefsey)	Tablets: 200/25/25 mg
emtricitabine/rilpivirine/tenofovir disoproxil fumarate (Complera)	Tablets: 200/25/300 mg
ertugliflozin (Steglatro)	Tablets: 5 mg, 15 mg
ertugliflozin/metformin (Segluromet)	Tablets: 2.5/500 mg, 2.5/1000 mg, 7.5/500 mg, 7.5/1,000 mg
exemestane (Aromasin)	Tablets: 25 mg
ezetimibe (Zetia)	Tablets: 10 mg
ezetimibe/simvastatin (Vytorin)	Tablets (ezetimibe mg/simvastatin mg): 10/10, 10/20, 10/40, 10/80
fluticasone/vilanterol (Breo Ellipta)	Foil blister strips with inhalation powder containing fluticasone/salmeterol: 100/25 mcg, 200/25 mcg
lamotrigine (Lamictal XR)	Extended-release tablets: 25 mg, 50 mg, 100 mg, 200 mg, 250 mg, 300 mg

Drug Name	Availability
levetiracetam (Keppra XR)	Film-coated extended-release tablets: 500 mg, 750 mg
iodoxamide (Alomide)	0.1% ophthalmic solution: 10 mL
mesalamine (Apriso)	Extended-release (24 hr) capsules: 0.375 g
mesalamine (Asacol HD)	Delayed-release tablets: 800 mg
mesalamine (Delzicol)	Delayed-release capsules: 400 mg
mesalamine (Lialda)	Delayed-release tablets: 1.2 g
mesalamine (Pentasa)	Extended-release capsules: 250 mg, 500 mg
mometasone/formoterol (Dulera)	Inhalation aerosol containing mometasone/formoterol: 50/5 mcg, 100/5 mcg, 200/5 mcg
nedocromil (Alocril)	2% ophthalmic solution: 5 mL, 10 mL
olmesartan (Benicar)	Tablets: 5 mg, 20 mg, 40 mg
olmesartan/amlodipine/HCTZ (Tribenzor)	Tablets: 20/5/12.5 mg, 40/5/12.5 mg, 40/5/25 mg, 40/10/12.5 mg, 40/10/25 mg
olmesartan/HCTZ (Benicar HCT)	Tablets: 20/12.5 mg; 40/12.5 mg, 40/25 mg
rosuvastatin (Crestor)	Tablets: 5 mg, 10 mg, 20 mg, 40 mg

VI. References

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6. Steglatro Prescribing Information. Whitehouse Station, NJ: Merck & Co., Inc.; December 2017. Available at www.steglatro.com. Accessed August 27, 2018.

Reviews, Revisions, and Approvals	Date	P&T Approval Date
Policy created	12.28.17	05.18
3Q 2018 annual review: CP.PST.03 added; references reviewed and updated.	04.11.18	08.18
4Q 2018 annual review: CP.PST.05 added; references reviewed and updated.	07.26.18	11.18
Changes align with previously approved clinical guidance: Added Atripla, Odefsey, and Complera to policy requiring step through	10.17.18	

Reviews, Revisions, and Approvals	Date	P&T Approval Date
Symfi if member is treatment naïve per SDC; added continuation of care language for HIV per SDC.		
Changes align with previously approved clinical guidance: added Steglatro and Segluromet per SDC decision.	10.17.18	
1Q 2019 annual review: CP.PST.08 added; modified minimum A1c related to concurrent use of metformin from 9% to 8.5% based on 2019 ADA guidelines; references reviewed and updated.	10.30.18	02.19
Changes align with previously approved clinical guidance: added Symtuza to policy requiring step through Symfi if member is treatment naïve per SDC.	12.18.18	
Changes align with previously approved clinical guidance: added Delstrigo to policy requiring step through Symfi if member is treatment naïve per SDC.	02.01.19	
Changes align with previously approved clinical guidance: added Zetia and Vytorin to policy requiring step through generic statin or previous treatment with ezetimibe; archived CP.PMN.77 Vytorin and CP.PMN.78 Zetia policies.	03.04.19	
Added disclaimer statement that policy does not apply to NF drugs.	05.21.19	
1Q 2020 annual review: Changes align with previously approved clinical guidance and SDC decision: added Dulera, Symbicort, and Breo Ellipta to policy requiring step through fluticasone/salmeterol (generic Advair).	01.03.20	02.20
Per February SDC and prior clinical guidance for Dulera and Breo Ellipta: added additional step through option of budesonide/formoterol (generic Symbicort); removed Symbicort stepping through generic Advair; and retire CP.PMN.228.	03.26.20	

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.

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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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