Clinical Policy: Step Therapy
Reference Number: HIM.PA.109
Effective Date: 08.01.17
Last Review Date: 05.19
Line of Business: HIM

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.

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 12 months 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.

<table>
<thead>
<tr>
<th>Drug Name</th>
<th>Required Step-Through Agents</th>
<th>Maximum Dose (Quantity Limit)</th>
<th>Age Limit</th>
</tr>
</thead>
<tbody>
<tr>
<td>Edarbi® (azilsartan medoxomil)</td>
<td>Two of the following: candesartan, irbesartan, or losartan</td>
<td>80 mg daily (1 tablet/day)</td>
<td>N/A</td>
</tr>
<tr>
<td>amlodipine/olmesartan (Azor®)</td>
<td>Losartan or irbesartan</td>
<td>10/40 mg daily</td>
<td>N/A</td>
</tr>
<tr>
<td>amlodipine/olmesartan/HCTZ (Tribenzor®)</td>
<td>Losartan or irbesartan</td>
<td>10/40/25 mg daily</td>
<td>N/A</td>
</tr>
<tr>
<td>lovastatin SR (Altoprev®)</td>
<td>Two of the following: atorvastatin, lovastatin IR, pravastatin, or simvastatin</td>
<td>60 mg daily (1 tablet/day)</td>
<td>N/A</td>
</tr>
<tr>
<td>Livalo® (pitavastatin calcium)</td>
<td>Two of the following: atorvastatin, lovastatin IR, pravastatin, or simvastatin</td>
<td>4 mg daily (1 tablet/day)</td>
<td>N/A</td>
</tr>
<tr>
<td>Drug Name</td>
<td>Required Step-Through Agents</td>
<td>Maximum Dose (Quantity Limit)</td>
<td>Age Limit</td>
</tr>
<tr>
<td>---------------------------------</td>
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</tr>
<tr>
<td>Dexilant™ (dexlansoprazole DR)</td>
<td>Two of the following: lansoprazole, omeprazole, pantoprazole, or rabeprazole</td>
<td>60 mg daily (1 tablet/day)</td>
<td>N/A</td>
</tr>
<tr>
<td>venlafaxine SR (Effexor ER®)</td>
<td>Venlafaxine IR</td>
<td>225 mg daily (1 tablet/day)</td>
<td>N/A</td>
</tr>
<tr>
<td>Equetro® (carbamazepine SR)</td>
<td>Carbamazepine IR</td>
<td>1,600 mg daily (two 100 mg tablets/day, eight 200 mg tablets/day, or four 300 mg tablets/day)</td>
<td>N/A</td>
</tr>
<tr>
<td>eszopiclone (Lunesta®)</td>
<td>Zaleplon and zolpidem tartrate</td>
<td>3 mg daily for adults, 2 mg daily for geriatric (1 tablet/day)</td>
<td>≥ 18 years</td>
</tr>
<tr>
<td>zolpidem tartrate ER (Ambien CR®)</td>
<td>Zolpidem IR</td>
<td>12.5 mg daily (1 tablet/day)</td>
<td>N/A</td>
</tr>
<tr>
<td>Rozerem® (ramelteon)</td>
<td>Zaleplon and zolpidem</td>
<td>8 mg daily (1 tablet/day)</td>
<td>≥ 18 years</td>
</tr>
<tr>
<td>Vyvanse® (lisdexamfetamine dimesylate)</td>
<td>Generic Adderall XR®</td>
<td>70 mg daily (1 tablet/day)</td>
<td>N/A</td>
</tr>
<tr>
<td>dihydroergotamine mesylate (Migranal®)</td>
<td>Two of the following: naratriptan, rizatriptan, or sumatriptan</td>
<td>2 sprays in each nostril per migraine episode, up to a total of 3 mg/24 hours and 4 mg/week (1 mg or 0.267 mL/day)</td>
<td>N/A</td>
</tr>
<tr>
<td>almotriptan malate (Axert®)</td>
<td>Two of the following: naratriptan, rizatriptan, or sumatriptan</td>
<td>25 mg daily (0.3 tablet/day for 6.25 mg, 0.4 tablet/day for 12.5 mg)</td>
<td>≥ 12 years</td>
</tr>
<tr>
<td>eletriptan (Relpax®)</td>
<td>Two of the following: naratriptan, rizatriptan, or sumatriptan</td>
<td>80 mg daily (0.2 tablet/day)</td>
<td>≥ 18 years</td>
</tr>
<tr>
<td>frovatriptan succinate (Frova®)</td>
<td>Two of the following: naratriptan, rizatriptan, or sumatriptan</td>
<td>7.5 mg daily (0.4 tablet/day)</td>
<td>≥ 18 years</td>
</tr>
<tr>
<td>zolmitriptan (Zomig®, Zomig ZMT®)</td>
<td>Two of the following: naratriptan, rizatriptan, or sumatriptan</td>
<td>5 mg per dose, up to 10 mg daily (0.3 tablet/day)</td>
<td>≥ 12 years</td>
</tr>
<tr>
<td>Drug Name</td>
<td>Required Step-Through Agents</td>
<td>Maximum Dose (Quantity Limit)</td>
<td>Age Limit</td>
</tr>
<tr>
<td>-----------------------------------------------</td>
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<td>-----------</td>
</tr>
<tr>
<td>Aptom® (eslicarbazepine)</td>
<td>Carbamazepine or oxcarbazepine</td>
<td>1,600 mg daily (2 tablets/day)</td>
<td>N/A</td>
</tr>
<tr>
<td>ropinirole ER (Requip® XL)</td>
<td>Requip® IR</td>
<td>24 mg daily (1 tablet/day for 2 mg, 4 mg, 6 mg; 2 tablets/day for 8 mg, 12 mg)</td>
<td>N/A</td>
</tr>
<tr>
<td>Lumigan® (bimatoprost ophthalmic solution 0.01%)</td>
<td>Latanoprost</td>
<td>1 drop daily in each affected eye</td>
<td>N/A</td>
</tr>
<tr>
<td>adapalene gel 0.3%, adapalene lotion 0.1% (Differin®)</td>
<td>Two of the following: topical benzoyl peroxide, clindamycin, erythromycin, or tretinoin</td>
<td>1 application to affected area daily</td>
<td>≥ 12 years</td>
</tr>
<tr>
<td>Azelex® (azelaic acid cream)</td>
<td>Two of the following: topical benzoyl peroxide, clindamycin, erythromycin, or tretinoin</td>
<td>2 applications daily</td>
<td>≥ 12 years</td>
</tr>
<tr>
<td>adapalene/benzoyl peroxide (Epiduo®)</td>
<td>Two of the following: topical benzoyl peroxide, clindamycin, erythromycin, or tretinoin</td>
<td>1 application daily</td>
<td>≥ 12 years</td>
</tr>
<tr>
<td>clindamycin phosphate/tretinoin gel (Veltin®, Ziana®)</td>
<td>Two of the following: topical benzoyl peroxide, clindamycin, erythromycin, or tretinoin</td>
<td>1 application to affected area daily</td>
<td>≥ 12 years</td>
</tr>
<tr>
<td>sulfacetamide sodium with sulfur wash (Sumadan Wash®)</td>
<td>Two of the following: topical benzoyl peroxide, clindamycin, erythromycin, or tretinoin</td>
<td>2 applications daily</td>
<td>≥ 12 years</td>
</tr>
<tr>
<td>clobetasol propionate (Olux®, Temovate®)</td>
<td>Clobetasol cream/solution/ointment or desonide ointment</td>
<td>50 mL/week scalp or topical solutions and shampoo; 59 mL/week spray solution; 50 g/week other topicals (foam 3 g/day, gel 2 g/day)</td>
<td>N/A</td>
</tr>
<tr>
<td>calcipotriene/betamethasone</td>
<td>Calcipotriene and betamethasone</td>
<td>100 g per week topically, or 60 g</td>
<td>N/A</td>
</tr>
</tbody>
</table>
### Step Therapy

<table>
<thead>
<tr>
<th>Drug Name</th>
<th>Required Step-Through Agents</th>
<th>Maximum Dose (Quantity Limit)</th>
<th>Age Limit</th>
</tr>
</thead>
<tbody>
<tr>
<td>Dipropionate (Taclonex®)</td>
<td>Dipropionate as a separate agents</td>
<td>Foam every 4 days topically; treatment of more than 30% body surface area not recommended</td>
<td></td>
</tr>
<tr>
<td>Cefixime for suspension (Suprax®)</td>
<td>Cefdinir or cefpodoxime</td>
<td>400 mg daily; 8 mg/kg/day if a child weighing ≤ 45 kg</td>
<td>N/A</td>
</tr>
<tr>
<td>Fenoprofen calcium (Nalfon, Profeno®)</td>
<td>Ibuprofen</td>
<td>3,200 mg daily (4 tablets/day)</td>
<td>N/A</td>
</tr>
<tr>
<td>Mefenamic acid (Ponstel®)</td>
<td>Ibuprofen</td>
<td>1,250 mg daily (5 capsules/day)</td>
<td>N/A</td>
</tr>
<tr>
<td>Nevanac®, Ilevro® (nepafenac ophthalmic suspension)</td>
<td>Diclofenac ophthalmic or ketorolac ophthalmic</td>
<td>0.1%: 3 drops daily each affected eye; 0.3%: 1 drop daily each affected eye (0.2 mL/day)</td>
<td>N/A</td>
</tr>
<tr>
<td>Symtuza™ (darunavir/cobicistat/emtricitabine/tenofovir alafenamide)</td>
<td>If treatment naïve: Symfi or Symfi Lo (efavirenz/lamivudine/tenofovir disoprol fumarate) If treatment experienced: any HIV antiretroviral agent</td>
<td>800/150/200/10 mg daily (1 tablet/day)</td>
<td>N/A</td>
</tr>
<tr>
<td>Delstrigo™ (doravirine/lamivudine/tenofovir disoprol fumarate)</td>
<td>If treatment naïve: Symfi or Symfi Lo (efavirenz/lamivudine/tenofovir disoprol fumarate) If treatment experienced: any HIV antiretroviral agent</td>
<td>100/300/300 mg daily (1 tablet/day)</td>
<td>N/A</td>
</tr>
<tr>
<td>Steglatro™ (ertugliflozin)</td>
<td>Metformin</td>
<td>15 mg daily (1 tablet/day)</td>
<td>N/A</td>
</tr>
</tbody>
</table>

Drugs 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.

**Approval duration:** 12 months

### 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 Symtuza or Delstrigo for HIV infection and has received this medication for at least 30 days;

2. If request is for a dose increase, new dose does not exceed the FDA-approved maximum recommended dose and quantity limit as stated in the initial approval criteria for the relevant drug.

**Approval duration: 12 months**

### III. Appendices/General Information

**Appendix A: Abbreviation/Acronym Key**

<table>
<thead>
<tr>
<th>Abbreviation</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>FDA</td>
<td>Food and Drug Administration</td>
</tr>
<tr>
<td>IR</td>
<td>Immediate release</td>
</tr>
<tr>
<td>ER</td>
<td>Extended release</td>
</tr>
<tr>
<td>DR</td>
<td>Delayed release</td>
</tr>
<tr>
<td>SR</td>
<td>Sustained release</td>
</tr>
<tr>
<td>XL</td>
<td>Extended release</td>
</tr>
<tr>
<td>CR</td>
<td>Controlled release</td>
</tr>
</tbody>
</table>

**Appendix B: Therapeutic Alternatives**

Refer to required step-through drugs above in Section I.

**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

<table>
<thead>
<tr>
<th>Drug Name</th>
<th>Availability</th>
</tr>
</thead>
<tbody>
<tr>
<td>Edarbi (azilsartan medoxomil)</td>
<td>Tablets: 40, 80 mg</td>
</tr>
<tr>
<td>lovastatin SR (Altoprev)</td>
<td>Tablets: 20, 40, 60 mg</td>
</tr>
<tr>
<td>Livalo (pitavastatin calcium)</td>
<td>Tablets: 1, 2, 4 mg</td>
</tr>
<tr>
<td>Dexilant (dexlansoprazole DR)</td>
<td>Capsules: 30, 60 mg</td>
</tr>
<tr>
<td>venlafaxine SR (Effexor ER)</td>
<td>Tablets: 37.5, 75, 150, 225 mg</td>
</tr>
<tr>
<td>eszopiclone (Lunesta)</td>
<td>Tablets: 1, 2, 3 mg</td>
</tr>
<tr>
<td>Rozerem (ramelteon)</td>
<td>Tablets: 8 mg</td>
</tr>
<tr>
<td>Vyvanse (lisdexamfetamine dimesylate)</td>
<td>Capsules: 10, 20, 30, 40, 50, 60, 70 mg</td>
</tr>
<tr>
<td>almotriptan malate (Axert)</td>
<td>Tablets: 6.25, 12.5 mg</td>
</tr>
<tr>
<td>eletriptan (Relpax)</td>
<td>Tablets: 20, 40 mg</td>
</tr>
<tr>
<td>frovatriptan succinate (Frova)</td>
<td>Tablets: 2.5 mg</td>
</tr>
<tr>
<td>zolmitriptan (Zomig, Zomig ZMT)</td>
<td>Tablets: 5 mg Nasal solution*: 2.5, 5 mg/spray ODT (ZMT): 2.5, 5 mg</td>
</tr>
<tr>
<td>Aptiom (eslicarbazepine)</td>
<td>Tablets: 200, 400, 600, 800 mg</td>
</tr>
<tr>
<td>ropinirole SR (Requip XL)</td>
<td>Tablets: 2, 4, 6, 8, 12 mg</td>
</tr>
<tr>
<td>bimatoprost ophth soln 0.01% (Lumigan)</td>
<td>Bottle: 0.01% solution</td>
</tr>
<tr>
<td>adapalene gel (Differin)</td>
<td>Topical cream, gel, lotion: 0.1%</td>
</tr>
<tr>
<td>Drug Name</td>
<td>Availability</td>
</tr>
<tr>
<td>------------------------------------------------</td>
<td>---------------------------------------------------</td>
</tr>
</tbody>
</table>
| Azelex (azelaic acid cream)                    | Topical gel: 03%  
Topical gel pump: 0.3%                         |
| adapalene/benzoyl peroxide (Epiduo)            | Topical gel: 0.1%-2.5%  
Topical gel forte pump: 0.3%-2.5%  
Topical gel pump*: 0.1%-2.5%                  |
| clindamycin phosphate/tretinoin gel (Veltin, Ziana) | Topical gel: 1.2%-0.025%                         |
| sulfacetamide sodium with sulfur wash (Sumadan Wash) | Topical wash: 9%-4.5%                            |
| clobetasol propionate (Olux)                  | Topical foam: 0.05%  
Topical gel: 0.05%                              |
| calcipotriene/betamethasone dipropionate (Taclonex) | Topical ointment: 0.005%-0.064%  
Topical suspension: 0.005%-0.064%  
Topical foam: 0.005%-0.064%                    |
| cefixime for suspension (Suprax)               | Oral suspension: 100/5, 200/5, 500/5 mg/mL         |
| fenoprofen calcium (Profeno)                   | Tablets: 600 mg                                   |
| mefanamic acid (Ponstel)                       | Capsules: 250 mg                                  |
| Nevanac, Ilevro (nepafenac ophthalmic suspension) | Nevanac ophthalmic suspension: 0.1%  
Ilevro ophthalmic suspension: 0.3%            |
| Symtuza (darunavir/cobicistat/emtricitabine/tenofovir alafenamide) | Tablets: 800/150/200/10 mg                       |
| Delstrigo (doravirine/lamivudine/tenofovir disoproxil fumarate) | Tablets: 100/300/300 mg                          |
| Steglatro (ertugliflozin)                      | Tablets: 5 mg, 15 mg                              |
| amlodipine/olmesartan (Azor)                   | Tablets: 5/20, 5/40, 10/20, 10/40 mg              |
| olmesartan/amldipine/HCTZ (Tribenzor)          | Tablets: 20/5/12.5, 40/10/12.5, 4/10/25, 40/5/12.5, 40/5/25 mg |
| Eequetro (carbamazepine SR)                    | Capsules: 100, 200, 300 mg                        |
| zolpidem tartrate ER (Ambien CR)               | Tablets: 6.25, 12.5 mg                            |
| dihydroergotamine mesylate (Migranal)          | Nasal spray: 4 mg/mL                              |

*Available as branded product only

VII. References
CLINICAL POLICY
Step Therapy

<table>
<thead>
<tr>
<th>Reviews, Revisions, and Approvals</th>
<th>Date</th>
<th>P&amp;T Approval Date</th>
</tr>
</thead>
<tbody>
<tr>
<td>Policy created. Converted to new template; added max dose.</td>
<td>06.17</td>
<td>08.17</td>
</tr>
<tr>
<td>Q2 2018 annual review: generic step therapy criteria is replaced with actual step through requirement for specific drugs requiring step therapy</td>
<td>03.12.18</td>
<td>05.18</td>
</tr>
<tr>
<td>No significant changes: changes in this document is covered by P&amp;T approved clinical guidance/formulary: The following drugs are removed from the list due to the stated reasons: Lantus is NF; Vascepa is PA, Not EST; Zegerid is blocked, not EST; prescription Nexium is blocked not EST; Ndihydroergotamine mesylate nasal spray (Dihydroergotamine Mesylate®, Migranal®) no longer requires EST.</td>
<td>07.06.18</td>
<td></td>
</tr>
<tr>
<td>No significant changes: specified adapalene gel 0.3% and adapalene lotion 0.1% for clarity; added age limits per formulary; The following drugs are removed from the list due to the stated reasons: Pentasa and Delzicol are NF, and Oleptro is no longer available on the market; corrected max dose of Altoprev.</td>
<td>10.03.18</td>
<td></td>
</tr>
<tr>
<td>Changes align with previously approved clinical guidance: added Symtuza to policy requiring step through Symfi if member is treatment naïve per SDC; added continuation of care language for HIV per SDC.</td>
<td>12.19.18</td>
<td></td>
</tr>
<tr>
<td>Changes align with previously approved clinical guidance: added Delstrigo to policy requiring step through Symfi if member is treatment naïve per SDC.</td>
<td>02.01.19</td>
<td></td>
</tr>
<tr>
<td>2Q 2019 annual review: no significant changes; added Azor, Equetro, Migranal, Tribenzor and modified requirement for clobetasol to align with currently programmed step therapy edits; references reviewed and updated.</td>
<td>02.01.19</td>
<td>05.19</td>
</tr>
<tr>
<td>Changes align with previously approved clinical guidance and currently existing programming: added Steglatro requiring step through of metformin per HIM formulary changes.</td>
<td>03.01.19</td>
<td></td>
</tr>
<tr>
<td>Removed Vytorin from policy per SDC.</td>
<td>03.04.19</td>
<td></td>
</tr>
</tbody>
</table>

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.

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Note:
For Health Insurance Marketplace members, when applicable, this policy applies only when the prescribed agent is on your health plan approved formulary. Request for non-formulary drugs must be reviewed using the non-formulary policy; HIM.PA.103.

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