VENTURA COUNTY HEALTH CARE PLAN

VCHCP Step Therapy Policy

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STEP THERAPIES*

Angiotensin Receptor Blocker (ARB) Step Therapy Program

POLICY: Angiotensin Receptor Blocker Step Therapy Policy

Single-Entity Products

- Atacand® (candesartan tablets – AstraZeneca/Ani, generic)
- Avapro® (irbesartan tablets – sanofi-aventis, generic)
- Benicar® (olmesartan tablets – Cosette, generic)
- Cozaar® (losartan tablets – Organon, generic)
- Diovan® (valsartan tablets – Novartis, generic)
- Edarbi® (azilsartan tablets – Takeda/Arbor)
- eprosartan tablets – generic
- Micardis® (telmisartan tablets – Boehinger-Ingelheim, generic)

Combination Products

- Atacand HCT® (candesartan/hydrochlorothiazide tablets – AstraZeneca, generic)
- Avalide® (irbesartan/hydrochlorothiazide tablets – sanofi-aventis, generic)
- Azor® (olmesartan/amlodipine tablets – Cosette, generic)
- Benicar HCT® (olmesartan/hydrochlorothiazide tablets – Cosette, generic)
- Diovan HCT® (valsartan/hydrochlorothiazide tablets – Novartis, generic)
- Edarbyclor® (azilsartan/chlorthalidone tablets – Takeda/Arbor)
- Exforge® (valsartan/amlodipine tablets – Novartis, generic)
- Exforge HCT® (valsartan/amlodipine/hydrochlorothiazide tablets – Novartis, generic)Hyzaar® (losartan/hydrochlorothiazide tablets – Merck, generic)
- Micardis® HCT (telmisartan/hydrochlorothiazide tablets – Boehringer Ingelheim, generic)

- Prexxartan® (valsartan oral solution – BioRamo/Medicure)
- Tribenzor® (olmesartan/amlodipine/hydrochlorothiazide tablets – Cosette, generic)
- Twynsta® (telmisartan/amlodipine tablets – Boehringer Ingelheim, generic)

Automation: A patient with a history of one Step 1 Product within the 130-day look-back period is excluded from Step Therapy.

Step 1: candesartan, candesartan/HCTZ, eprosartan, irbesartan, irbesartan/HCTZ, losartan, losartan/HCTZ, telmisartan, telmisartan/amlodipine, telmisartan/HCTZ, olmesartan, olmesartan/amlodipine, olmesartan/HCTZ, olmesartan/amlodipine/HCTZ, valsartan, valsartan/amlodipine, valsartan/HCTZ, valsartan/amlodipine/hydrochlorothiazide

Step 2: Atacand, Atacand HCT, Avalide, Avapro, Azor, Benicar, Benicar HCT, Cozaar, Diovan, Diovan HCT, Edarbi, Edarbyclor, Exforge, Exforge HCT, Hyzaar, Micardis, Micardis HCT, Tribenzor, Twynsta, valsartan oral solution

CRITERIA

1. If the patient has tried one Step 1 Product, approve a Step 2 Product.

2. Approve a Step 2 Product if the patient meets the following criteria (A, B, and C):
   A) The generic equivalent is not available in Step 1; AND
   B) Patient was hospitalized and discharged within the previous 30 days for a cardiovascular event; AND
   Note: Examples of a cardiovascular event include a myocardial infarction, a hypertensive emergency, and decompensated heart failure.

   C) Patient has been started and stabilized on the Step 2 Product.

3. If the patient cannot swallow or has difficulty swallowing tablets, approve valsartan oral solution.
4. No other exceptions are recommended.

Branded Nonsteroidal Anti-Inflammatory Drug (NSAID) Step Therapy Program:

NSAID	Product	Manufacturer
Diclofenac	Cataflam® tablets, generic	Novartis, generic
	diclofenac sodium delayed-release tablets (generic only)	Generic only
	Lofena™ tablets, generic	Carwin, generic
	Volatren® XR extended-release tablets (obsolete 03/01/2021), generic	Novartis, generic
	Zorvolex® capsules, authorized generic for 35 mg strength	Iroko Pharmaceuticals
	Zipsor® capsules	Assertio Therapeutics
	Cambia® oral solution	Assertio Therapeutics
	Arthrotec® (diclofenac and misoprostol tablets), generic	Pfizer, generic
	diclofenac 1.5% solution (generic only)	Generic only
	Flector® (diclofenac epolamine 1.3% topical patch), authorized generic	Institut Biochimique SA, generic
	Licart™ (diclofenac epolamine 1.3% topical system)	Institut Biochimique SA
	Pennsaid® (diclofenac sodium 2% topical solution, generic)	Horizon Pharma, generic
	Voltaren® Gel (diclofenac sodium 1% topical gel), generic	Endo Pharmaceuticals, generic
Etodolac	Lodine® tablets, generic	Sallus, generic
	etodolac capsules (generic only)	Generic only
	etodolac extended-release tablets (generic only)	Generic only
Fenoprofen	Nalfon® capsules and tablets (generic to tablets only)	Xspire, generic
	Fenortho® capsules	Sterling Knight Pharma
	Fenoprofen capsules (brand)	Various
Flurbiprofen	flurbiprofen tablets (generic only)	Generic only
Ibuprofen	ibuprofen capsules, tablets, and oral suspension	Generic only
	Duexis® (ibuprofen and famotidine tablets, generic)	Horizon Pharma, generic
Indomethacin	indomethacin capsules and extended-release capsules (generic only)	Generic only
	Indocin® oral suspension	Iroko Pharmaceuticals
	Tivorbex® capsules, authorized generic	Iroko Pharmaceuticals
Ketoprofen	ketoprofen capsules and extended-release capsules (generic only)	Generic only
Ketorolac	ketorolac tablets (generic only)	Generic only
	Sprix® (ketorolac nasal spray, authorized generic)	Egalet
Meclofenamate	meclofenamate capsules (generic only)	Generic only
Mefenamic acid	mefenamic acid capsules (generic only)	Generic only
Meloxicam	Mobic® tablets, generic	Boehringer Ingelheim, generic
	Qmiiz™ ODT (obsolete 04/01/2020)	TerSera Therapeutics
	Vivlodex™ capsules, generic	Iroko Pharmaceuticals, generic
	meloxicam oral suspension (generic)	Generic only
Nabumetone	Relafen® tablets, generic	Blucrest, generic
	Relafen® DS tablets	Carwin Associates
Naproxen	Naprosyn® tablets and oral suspension, generic	Canton Laboratories, generic
	EC-Naprosyn® delayed-release tablets, generic	Canton Laboratories, generic
	Anaprox DS® controlled-release tablets, generic	Canton Laboratories, generic
	Naprelan® controlled-release tablets, generic	Almatica Pharma, generic
	Vimovo® (naproxen and esomeprazole delayed-release tablets, generic)	Horizon Pharma, generic
Oxaprozin	Daypro® tablets, generic	Pfizer, generic
Piroxicam	Feldene® capsules, generic	Pfizer, generic
Sulindac	sulindac tablets (generic only)	Generic only
Tolmetin	tolmetin capsules and tablets (generic only)	Generic only

Automation: For single-entity NSAIDs (Step 2a), a patient with a history of two Step 1a Products within the 130-day look-back period is excluded from Step Therapy. (Note: naproxen/esomeprazole delayed-release tablets [Vimovo, generic] and ibuprofen/famotidine tablets [Duexis, generic] are not included in Step 2a.) For naproxen/esomeprazole delayed-release tablets (Vimovo, generic) [Step 2b], a patient with a history of one prescription PPI and one naproxen product within the 130-day look-back period is excluded from Step Therapy. For ibuprofen/famotidine tablets (Duexis, generic) [Step 2c], a patient with a history of one prescription H_2RA and one prescription oral ibuprofen product within the 130-day look-back period is excluded from Step Therapy.

Step 1a/2a

Step 1a NSAIDs:

- Cataflam
- diclofenac potassium 50 mg
- diclofenac potassium 25 mg capsules
- diclofenac sodium (IR and ER)
- diclofenac sodium and misoprostol
- diclofenac sodium topical solution 1.5%*
- etodolac (IR and ER)
- flurbiprofen
- ibuprofen
- indomethacin (IR and ER)
- ketoprofen IR 50 mg and 75 mg
- ketorolac (tablets)
- meclofenamate
- mefenamic acid
- meloxicam tablets
- nabumetone
- naproxen**
- oxaprozin
- piroxicam
- sulindac
- tolmetin 200 mg

Step 2a NSAIDs:

- Anaprox DS
- Arthrotec
- Cambia, diclofenac potassium powder packet
- Coxanto
- Daypro
- diclofenac potassium 25 mg tablets
- diclofenac sodium 1% topical gel*
- diclofenac sodium 2% topical solution*
- Feldene
- Fenoprofen (brand), fenoprofen 600 mg
- Fenortho
- Flector patch, diclofenac epolamine 1.3% patch*
- Indocin
- indomethacin oral suspension
- ketoprofen ER 200 mg
- ketoprofen IR 25 mg
- Licart*
- Lodine
- Lofena
- meloxicam capsules
- meloxicam suspension
- Mobic
- Nalfon
- Naprelan and generics
- Naprosyn, EC-Naprosyn, and generic suspension
- Pennsaid 2%*
- Qmiiz
- Relafen
- Relafen DS
- Sprix, ketorolac nasal spray
- Tivorbex, indomethacin 20 mg capsule
- tolmetin 400 mg, 600 mg
- Vivlodex
- Voltaren Gel 1%*
- Voltaren XR
- Zipsor
- Zorvolex, diclofenac 35 mg capsule

IR – Immediate-release; ER – Extended-release

* Denotes topical product

** Some generic naproxen products are Step 2a

Step 1b/2b

Step 1b (brand or generic):

- Prescription naproxen sodium
- Prescription naproxen

AND

- Prescription dexlansoprazole
- Prescription esomeprazole magnesium
- Prescription esomeprazole strontium
- Prescription lansoprazole
- Prescription omeprazole
- Prescription omeprazole magnesium
- Prescription omeprazole/sodium bicarbonate
- Prescription pantoprazole (oral)
- Prescription rabeprazole

Step 2b NSAID:
- Vimovo
- naproxen/esomeprazole delayed-release tablets

Step 1c/2c

Step 1c (brand or generic):

- Prescription ibuprofen (oral)

AND

- Prescription cimetidine (oral)
- Prescription famotidine (oral)
- Prescription nizatidine (oral)
- Prescription ranitidine (oral)

Step 2c NSAID:
- Duexis
- ibuprofen/famotidine tablets

CRITERIA

Step 2a NSAIDs

1. If the patient has tried two different Step 1a prescription-strength NSAIDs for the current condition, approve a Step 2a NSAID.
   Note: Celecoxib is accepted as a generic NSAID. Also, over-the-counter (OTC) NSAIDs count as alternatives if the patient used prescription-strength doses.

2. If the patient has tried ibuprofen suspension, approve naproxen suspension, meloxicam suspension, or Indocin suspension.
   Note: OTC ibuprofen suspension would count as an alternative.

3. If the patient has tried generic diclofenac sodium topical solution 1.5% and the patient has difficulty swallowing or cannot swallow tablets or liquid dosage forms (solution/suspension), approve ketorolac nasal spray (Sprix, authorized generic), Pennsaid 2%, diclofenac sodium 2% topical solution, Flector Patch, diclofenac epolamine 1.3% patch, Licart topical system, diclofenac sodium 1% topical gel, or Voltaren Gel.

4. If the patient has tried generic diclofenac sodium topical solution 1.5% and the patient has a chronic musculoskeletal pain condition (e.g., osteoarthritis) and is at risk of NSAID-associated toxicity, approve Pennsaid 2%, diclofenac sodium 2% topical solution, diclofenac sodium 1% topical gel, or Voltaren Gel.
   Note: Examples of risk factors of NSAID-associated toxicity include patients with a previous gastrointestinal bleed, history of peptic ulcer disease, impaired renal function, cardiovascular disease, hypertension, heart failure, elderly patients with impaired hepatic function, or taking concomitant anticoagulants.

5. If the patient has tried generic diclofenac sodium topical solution 1.5% and the patient has hand or knee osteoarthritis, approve Pennsaid 2%, diclofenac sodium 2% topical solution, diclofenac sodium 1% topical gel, or Voltaren Gel.

6. No other exceptions are recommended.

Vimovo and generic naproxen/esomeprazole delayed-release tablets

1. If the patient has tried one prescription proton pump inhibitor (PPI) [e.g., omeprazole, lansoprazole, pantoprazole] and one prescription naproxen product (brand or generic), approve naproxen/esomeprazole delayed-release tablets (Vimovo, generic).
   Note: Do not approve naproxen/esomeprazole delayed-release tablets (Vimovo, generic) if the patient has only tried over-the-counter (OTC) naproxen, NSAIDs other than naproxen, a COX-2 inhibitor (celecoxib), or OTC PPIs.
   Note: Separate prescription trials of a PPI and a naproxen product are required; a previous trial of Vimovo or generic naproxen/esomeprazole does not count.

2. No other exceptions are recommended.

Duexis and generic ibuprofen/famotidine tablets

1. If the patient has tried one prescription histamine$_2$ receptor antagonist (H_2RA) [e.g., famotidine, ranitidine, nizatidine] and one prescription ibuprofen product (brand or generic), approve ibuprofen/famotidine tablets (Duexis, generic).
   Note: Do not approve ibuprofen/famotidine tablets (Duexis, generic) if the patient has only tried over-the-counter (OTC) ibuprofen, NSAIDs other than ibuprofen, a COX-2 inhibitor (celecoxib), or OTC H_2RAs.
   Note: Separate prescription trials of an H_2RA and an ibuprofen product are required; a previous trial of Duexis or generic ibuprofen/famotidine does not count.

Cyclooxygenase-2 (COX-2) Inhibitor Step Therapy Program - RETIERED 9/1/2023

- Celebrex® (celecoxib capsules – Pfizer, generic)

Automation: The following automation is applied in this policy:

- **Step 2 (generic celecoxib):** A patient with a history of two Step 1 Products (oral NSAIDS) within the 130-day look-back period can receive the Step 2 Product (generic celecoxib). Alternatively, a patient with a history of one of the following within the 130-day look-back period: warfarin, clopidogrel, prasugrel, Brilinta™ (ticagrelor tablets), Xarelto® (rivaroxaban tablets and oral suspension), Pradaxa® (dabigatran capsules), Eliquis® (apixaban tablets), or Savaysa™ (edoxaban tablets) can receive the Step 2 Product (generic celecoxib).
- **Step 3 (brand Celebrex):** A patient with a history of two Step 1 Products (oral NSAIDS) and the Step 2 Product (generic celecoxib) within the 130-day look-back period can receive the Step 3 Product (brand Celebrex). Alternatively, a patient with the history of the Step 2 Product (generic celecoxib) and of one of the following, both within the 130-day look-back period: warfarin, clopidogrel, prasugrel, Brilinta™ (ticagrelor tablets), Xarelto® (rivaroxaban tablets and oral suspension), Pradaxa® (dabigatran capsules), Eliquis® (apixaban tablets), or Savaysa™ (edoxaban tablets) can receive the Step 3 Product (brand Celebrex).

Step 1 (oral NSAIDs):

- Cataflam
- diclofenac potassium
- diclofenac sodium (IR and ER)
- diclofenac sodium and misoprostol
- etodolac (IR and ER)
- fenoprofen
- flurbiprofen
- ibuprofen
- indomethacin (IR and ER)
- ketoprofen IR 50 mg and 75 mg
- ketorolac (tablets)
- meclofenamate
- mefenamic acid
- meloxicam
- nabumetone
- naproxen**
- oxaprozin
- piroxicam
- sulindac
- tolmetin**

**Some generic naproxen and tolmetin products are not Step 1 products

Step 2: generic celecoxib capsules

Step 3: brand Celebrex capsules

CRITERIA

1. Approve the Step 2 Product (generic celecoxib) for 1 year if the patient meets one of the following (A, B, C, D, or E):
- **A)** Patient has tried two Step 1 Products (oral NSAIDs), either as prescription products or as over-the-counter (OTC) products, at prescription-strength doses for the current condition; OR
- **B)** Patient is currently taking chronic systemic corticosteroid therapy (e.g., prednisone), warfarin, clopidogrel, prasugrel, Brilinta (ticagrelor tablets), Xarelto (rivaroxaban tablets and oral suspension), Pradaxa (dabigatran capsules), Eliquis (apixaban tablets), Savaysa (edoxaban tablets), chronic aspirin therapy, fondaparinux injection or a low molecular weight heparin product (i.e., enoxaparin injection, Fragmin [dalteparin injection]); OR
- **C)** Patient has reduced platelet counts or other coagulation disorders; OR
- **D)** Patient is > 75 years of age and is using celecoxib for a chronic condition; OR
- **E)** Patient has had a documented upper gastrointestinal bleed from a duodenal or gastric ulcer.

2. Approve the Step 2 Product (generic celecoxib) for 30 days if the patient is using the product during the preoperative/perioperative/postoperative period.

3. Approve the Step 3 Product (brand Celebrex) for 1 year if the patient meets the following (A and B):
- **A)** Patient meets one of the following (i, ii, iii, iv, or v):
  - **i.** Patient has tried two Step 1 products (oral NSAIDs) either as prescription products or as over-the-counter (OTC) products at prescription-strength doses, for the current condition; OR
  - **ii.** Patient is currently taking chronic systemic corticosteroid therapy (e.g., prednisone), warfarin, clopidogrel, prasugrel, Brilinta (ticagrelor tablets), Xarelto (rivaroxaban tablets and oral suspension), Pradaxa (dabigatran capsules), Eliquis (apixaban tablets), Savaysa (edoxaban tablets), chronic aspirin therapy, fondaparinux injection, or a low molecular weight heparin product (i.e., enoxaparin injection, Fragmin [dalteparin injection]); OR
  - **iii.** Patient has reduced platelet counts or other coagulation disorders; OR
  - **iv.** Patient is > 75 years of age and is using celecoxib for a chronic condition; OR
  - **v.** Patient has had a documented upper gastrointestinal bleed from a duodenal or gastric ulcer; AND
- **B)** Patient has tried the Step 2 Product (generic celecoxib).

4. Approve the Step 3 Product (brand Celebrex) for 30 days if the patient meets both of the following (A and B):
- **A)** Patient is using the product during the preoperative/perioperative/postoperative period.
- **B)** Patient has tried the Step 2 Product (generic celecoxib).

Dipeptidyl Peptidase-4 (DPP-4) Inhibitors Step Therapy Program

- Janumet® (sitagliptin/metformin tablets – Merck)
- Janumet® XR (sitagliptin/metformin extended-release tablets – Merck)
- Januvia® (sitagliptin tablets – Merck)
- Jentadueto® (linagliptin/metformin tablets – Boehringer Ingelheim)
- Jentadueto® XR (linagliptin/metformin extended-release tablets – Boehringer Ingelheim)
- Kazano™ (alogliptin/metformin tablets – Takeda, authorized generic)
- Kombiglyze® XR (saxagliptin/metformin extended-release tablets – AstraZeneca)
- Nesina® (alogliptin tablets – Takeda, authorized generic)
- Onglyza® (saxagliptin tablets – AstraZeneca)
- Oseni™ (alogliptin/pioglitazone tablets – Takeda, authorized generic)
- Tradjenta® (linagliptin tablets – Boehringer Ingelheim)

Automation: A patient with a history of one of the following within the 130-day look-back period is excluded from Step Therapy:

- One Step 1 Product; OR
- One of the following metformin-containing products: Glumetza ER, Riomet, metformin oral solution, Riomet ER, metformin extended-release (generics to Fortamet ER and Glumetza ER), glyburide/metformin, glipizide/metformin, Actoplus Met, pioglitazone/metformin, Invokamet, Invokamet XR, Synjardy, Synjardy XR, Xigduo XR, dapagliflozin/metformin extended-release (authorized generic to Xigduo XR), Segluromet; OR
- One Step 2 Product.

Step 1: generic metformin, generic metformin extended-release (generic to Glucophage XR only)

Step 2: Januvia, Janumet, Janumet XR, saxagliptin (Onglyza, generic), saxagliptin/metformin extended-release (Kombiglyze XR, generic), Tradjenta, Jentadueto, Jentadueto XR, alogliptin (Nesina, authorized generic), alogliptin/metformin (Kazano, authorized generic), alogliptin/pioglitazone (Oseni, authorized generic), sitagliptin (Zituvio, authorized generic), sitagliptin/metformin (authorized generic)

CRITERIA

1. If the patient has tried one Step 1 Product, approve a Step 2 Product.
Note: A trial of one of the following metformin-containing products also satisfies the requirement: Fortamet ER (obsolete), Glucophage (obsolete), Glucophage XR (obsolete), Glumetza ER, Riomet, metformin oral solution, Riomet ER, metformin extended-release (generics to Fortamet ER and Glumetza ER), glyburide/metformin, glipizide/metformin, Actoplus Met, pioglitazone/metformin, Actoplus Met XR (obsolete), repaglinide/metformin (obsolete), Invokamet, Invokamet XR, Synjardy, Synjardy XR, Xigduo XR, dapagliflozin/metformin extended-release (authorized generic to Xigduo XR), Segluromet.

2. If the patient has tried one Step 2 Product, approve the requested Step 2 Product.

3. If the patient is initiating dual (combination) therapy with a single-entity DPP-4 inhibitor (Januvia, saxagliptin [Onglyza, generic], Tradjenta, alogliptin [Nesina, authorized generic], or Zituvio) AND metformin, approve a single-entity DPP-4 inhibitor.

4. If the patient has a contraindication to metformin, according to the prescriber, approve a single-entity DPP-4 inhibitor.

Note: Examples of contraindications to metformin include acute or chronic metabolic acidosis, including diabetic ketoacidosis.

5. No other exceptions are recommended.

Sedative Hypnotics

POLICY: Sedative Hypnotics Step Therapy Policy

- Ambien® (zolpidem tablets – Sanofi-Aventis, generic)
- Ambien CR® (zolpidem extended-release tablets – Sanofi-Aventis, generic)
- Belsomra® (suvorexant tablets – Merck)
- Dayvigo® (lemborexant tablets – Eisai)
- Edluar® (zolpidem 5 and 10 mg sublingual tablets – Meda)
- Intermezzo® (zolpidem 1.75 and 3.5 mg sublingual tablets –Purdue, generic)
- Lunesta® (eszopiclone tablets – Sepracor, generic)
- Quviviq™ (daridorexant tablets – Idorsia)
- Rozerem® (ramelteon tablets – Takeda, generic)
- Silenor® (doxepin 3 mg and 6 mg tablets – Currax, generic)
- Sonata® (zaleplon capsules – King, generic)
- Zolpimist® (zolpidem oral spray – Aytu BioScience)

Automation: A patient with a history of one Step 1 Product within the 130-day look-back period is excluded from Step Therapy. For Silenor and generic doxepin 3 mg and 6 mg tablets, a patient who is ≥ 65 years of age will not be targeted by this Step Therapy program.

Step 1: generic eszopiclone tablets, generic ramelteon tablets, generic zaleplon capsules, generic zolpidem immediate-release tablets, generic zolpidem extended-release tablets, generic zolpidem sublingual tablets

Step 2: Ambien, Ambien CR, Belsomra, Dayvigo, Edluar, Intermezzo, Lunesta, Quviviq, Rozerem, Silenor, generic doxepin 3 mg and 6 mg tablets, Sonata, Zolpidem Capsule, Zolpimist

CRITERIA

1. If the patient has tried one Step 1 Product, approve a Step 2 Product.

2. If the patient has a documented history of substance use disorder, approve Silenor or generic doxepin 3 mg or 6 mg tablets.

3. If the patient is ≥ 65 years of age, approve Silenor or generic doxepin 3 mg or 6 mg tablets.

4. If the patient has difficulty swallowing or cannot swallow tablets/capsules, approve Edluar or Zolpimist.

5. No other exceptions are recommended.

Nasal Steroids Step Therapy Program

POLICY: Nasal Steroids Step Therapy Policy

- Beconase AQ® (beclomethasone nasal spray – GlaxoSmithKline)
- Dymista® (azelastine hydrochloride/fluticasone propionate nasal spray – MEDA, generic)
- flunisolide nasal spray (generic only)
- fluticasone propionate nasal spray (generic only)
- mometasone furoate nasal spray (generic only)
- Omnaris® (ciclesonide nasal spray – Covis)
- Qnasl®/Qnasl® Children's (beclomethasone dipropionate nasal aerosol – Teva)
- Ryaltris™ (olopatadine hydrochloride/mometasone furoate nasal spray – Hikma)
- Xhance® (fluticasone propionate nasal spray – OptiNose)
- Zetonna® (ciclesonide nasal aerosol – Covis)

Automation: A patient with a history of one Step 1 drug within the 130-day look-back period is excluded from step therapy.

Step 1: fluticasone propionate nasal spray

Step 2: azelastine hydrochloride/fluticasone propionate nasal spray, Beconase AQ, Dymista, flunisolide nasal spray, mometasone furoate nasal spray, Omnaris, Qnasl, Qnasl Children's, Ryaltris, Xhance, Zetonna

CRITERIA

1. If the patient has tried one Step 1 Product, approve a Step 2 Product.

2. If the patient is < 4 years of age, approve mometasone furoate nasal spray.

3. No other exceptions are recommended.

Tetracyclines (oral) Step Therapy Program

Note: This policy targets only solid dosage forms priced as brand products.

- Acticlate™ (doxycycline hyclate tablets – Almirall, generic)
- Avidoxy™ DK Kit (doxycycline monohydrate tablets – Avidas)
- Doryx® DR (doxycycline hyclate delayed-release tablets – Mayne, generic)
- Doryx® MPC (doxycycline hyclate delayed-release tablets – Mayne)
- Doxycycline IR-DR 40 mg capsules (Owen [brand product])
- Minolira™ (minocycline extended-release tablets – EPI Health)
- Monodox® (doxycycline monohydrate capsules – Almirall, generic)
- Morgidox® Kit (doxycycline hyclate capsules – Medimetriks)
- Oracea™ (doxycycline delayed-release capsules – Galderma)
- Seysara™ (sarecycline tablets – Almirall)
- Solodyn® (minocycline hydrochloride extended-release tablets – Bausch Health, generic)
- Targadox™ (doxycycline hyclate tablets – Journey Medical)
- Vibramycin® (doxycycline hyclate capsules – Pfizer, generic)
- Ximino™ (minocycline hydrochloride extended-release capsules – Ohm)

Automation: A patient with a history of one Step 1 Product within the 130-day look-back period is excluded from Step Therapy.

Step 1:

Product Name and Formulation	Strengths
Demeclocycline tablets	All strengths
Doxycycline hyclate tablets	20 mg, 100 mg
Doxycycline hyclate/ Morgidox capsules	50 mg, 100 mg
Doxycycline monohydrate capsules/tablets	50 mg, 75 mg, 100 mg, 150 mg (tablet only)
Doxycycline monohydrate/Avidoxy tablets	All strengths
Doxycycline monohydrate/Mondoxyne capsules	50 mg, 75 mg, 100 mg
Doxycycline monohydrate suspension	All strengths
Minocycline hydrochloride IR capsules	All strengths
Minocycline hydrochloride IR tablets	All strengths
Tetracycline hydrochloride capsules	All strengths

IR – Immediate release.

Step 2:

Product Name and Formulation	Strengths
Acticlate tablets	75mg, 150 mg (brand and generic)
Avidoxy DK Kit	brand
Doryx DR tablets	50 mg, 80 mg, 200 mg (brand and generic)
Doryx MPC tablets	60 mg (brand), 120 mg (brand)
doxycycline hyclate DR tablets	75 mg, 100 mg (generic)
doxycycline hyclate DR tablets/Soloxide	150 mg (generic)
Doxycycline IR-ER capsules	Authorized generic
doxycycline monohydrate capsules	150 mg (generic)
Minolira ER tablets	105 mg, 135 mg (brand)
Monodox capsules	50 mg, 75 mg, 100 mg (brand)
Morgidox-Kit	50 mg, 100 mg (brand)
Oracea	40 mg (brand)
Seysara tablets	60 mg, 100 mg, 150 mg (brand)
Solodyn ER tablets	55 mg, 65 mg, 80 mg, 105 mg, 115 mg (brand and generic)
Targadox tablets	50 mg (brand and generic)
Tetracycline hydrochloride tablets	250 mg, 500 mg
Vibramycin cap, suspension, syrup	100 mg capsules, 50 mg/5 ml syrup (brand)
Ximino ER capsules	45 mg, 90 mg, 135 mg (brand and authorized generic)

IR – Immediate-release; DR – Delayed-release; ER – Extended-release.

CRITERIA

1. If the patient has tried one Step 1 Product, approve a Step 2 Product.

2. No other exceptions are recommended.

Antidepressants Step Therapy Policy

Medications	Manufacturer	Generic Availability
Bupropion Medications		
Aplenzin® (bupropion hydrobromide extended-release tablets)	Bausch Health	
Auvelity™ (dextromethorphan hydrobromide and bupropion hydrochloride extended-release tablets)	Axsome	
Bupropion XL tablets (brand products, authorized generic to Forfivo XL)	various	
Forfivo XL (bupropion hydrochloride extended-release tablets)	Almatica	
Wellbutrin SR® (bupropion hydrochloride sustained-release tablets)	GlaxoSmithKline	X
Wellbutrin XL® (bupropion hydrochloride extended-release tablets)	Bausch Health	X
Selective Serotonin Reuptake Inhibitor Medications		
Brisdelle® (paroxetine mesylate 7.5 mg capsules) [brand discontinued 5/2022]	Sebela	X
Celexa® (citalopram tablets and oral solution)	Allergan	X
Citalopram capsules (brand product)	Almatica	
Fluoxetine capsules (generic to discontinued Sarafem® capsules) [brand discontinued 12/2021]		X
Fluoxetine delayed-release capsules (generic to discontinued Prozac® Weekly™)		X
Fluoxetine tablets (generic only)		X
Fluvoxamine extended-release capsules (generic only)		X
Fluvoxamine tablets (generic only)		X
Lexapro® (escitalopram tablets and oral solution)	Allergan	X
Paxil® (paroxetine hydrochloride tablets and oral suspension)	Apotex	X
Paxil CR® (paroxetine hydrochloride controlled-release tablets)	Apotex	X
Pexeva® (paroxetine mesylate tablets) [discontinued 5/2023]	Sebela	
Prozac® (fluoxetine capsules, tablets, and oral solution)	Lilly	X
Sertraline capsules	Almatica/Viking	
Trintellix™ (vortioxetine tablets)	Takeda	
Viibryd® (vilazodone hydrochloride tablets)	Allergan	X
Zoloft® (sertraline tablets and oral solution)	Pfizer	X
Serotonin and Norepinephrine Reuptake Inhibitor Medications		
Cymbalta® (duloxetine delayed-release capsules)	Lilly	X
Desvenlafaxine extended-release tablets (brand product)	Alembic /Ranbaxy	
Drizalma Sprinkle™ (duloxetine delayed-release capsules)	Sun	
Effexor XR® (venlafaxine extended-release capsules)	Wyeth	X
Fetzima™ (levomilnacipran extended-release capsules)	Forest	
Pristiq® (desvenlafaxine succinate extended-release tablets)	Wyeth	X
Savella® (milnacipran tablets)	Forest	
Venlafaxine besylate extended-release tablets (brand product)	Almatica	
Venlafaxine HCl immediate-release tablets (generic only)		X
Venlafaxine HCl extended-release tablets (generic only)		X

Table 1. Available Long-Acting Bupropion-Containing Products.[1-5]

Brand / Generic name	Formulation	Strengths	Notes
Aplenzin® (bupropion HBr)	ER tablets	174, 348, 522 mg	Strengths are equivalent to 150, 300, and 450 mg of bupropion HCl, respectively.
Auvelity™ (dextromethorphan HBr and bupropion HCl)	ER tablets	45 mg/105 mg	Bupropion increases plasma levels of dextromethorphan by competitively inhibiting CYP2D6, which catalyzes a major biotransformation pathway for dextromethorphan.
Forfivo XL (bupropion HCl), authorized generics	ER tablets	450 mg	Use another bupropion formulation for initial dose titration. Patients being treated with other bupropion products at 450 mg/day can be switched to equivalent dose of Forfivo XL once daily.
Wellbutrin SR® (bupropion HCl), generic	SR tablets	100, 150, 200 mg	Available generically.
Wellbutrin XL® (bupropion HCl), generic	ER tablets	150, 300 mg	Available generically.

HBr – Hydrobromide; HCl – Hydrochloride; ER – Extended-release; CYP – Cytochrome P450; SR – Sustained-release.

Table 2. FDA-Approved Indications for the SSRIs.[7-21]

Brand (generic)	MDD	OCD	Panic Disorder	Bulimia Nervosa	PTSD	SAD	GAD	PMDD	VMS
Brisdelle® (paroxetine mesylate 7.5 mg capsules, generic)									X
Celexa® (citalopram tablets and oral solution, generic) and citalopram capsules	X								
Fluoxetine delayed-release capsules (generic to Prozac® Weekly™)	X*								
Fluvoxamine extended-release capsules (generic only)		X†				X			
Fluvoxamine (generic only)		X†							
Lexapro® (escitalopram tablets and oral solution, generic)	Xα						X^		
Paxil® (paroxetine HCl tablets and oral suspension, generic)	X	X	X		X	X	X		
Paxil CR® (paroxetine HCl controlled-release tablets, generic)	X		X			X		X	
Pexeva® (paroxetine mesylate tablets)	X	X	X				X		
Prozac® (fluoxetine capsules, tablets, and oral solution, generic)	X†	X†	X	X					
Sarafem® (fluoxetine capsules and tablets, generic only)								X	
Sertraline capsules	X	X†							
Trintellix™ [vortioxetine tablets]	X								
Viibryd® (vilazodone tablets, generic)	X								
Zoloft® (sertraline tablets and oral suspension, generic)	X	X†	X		X	X		X	

SSRIs – Selective serotonin reuptake inhibitors; MDD – Major depressive disorder; OCD – Obsessive compulsive disorder; PTSD – Posttraumatic stress disorder; SAD – Social anxiety disorder; GAD – Generalized anxiety disorder; PMDD – Premenstrual dysphoric disorder; VMS – Vasomotor symptoms; * Approved for the prevention of relapse during the continuation treatment phase of depression; † FDA-approved indication includes children and adolescents; α FDA-approved indication includes adolescents 12 to 17 years of age; ^ FDA-approved indication includes children and adolescents 7 to 17 years of age; CR – Controlled release; HCl – Hydrochloride.

Table 3. FDA-Approved Indications for the SNRIs in Adults.[22-31]

Brand (generic)	MDD	GAD	SAD	Panic Disorder	DPN Pain	Chronic Musculoskeletal Pain	Fibro-myalgia
Cymbalta® (duloxetine delayed-release capsules, generic)	X	X^			X	X	X*
Desvenlafaxine extended-release tablets (Brand product)	X						
Drizalma Sprinkle™ (duloxetine delayed-release capsules)	X	X^			X	X	
Effexor XR® (venlafaxine extended-release capsules, generic)	X	X	X	X			
Fetzima™ (levomilnacipran extended-release capsules)	X						
Pristiq® (desvenlafaxine succinate extended-release tablets, generic)	X						
Savella® (milnacipran tablets)							X
Venlafaxine besylate extended-release tablets (brand product)	X	X					
Venlafaxine HCl immediate-release tablets (generic only)	X						
Venlafaxine HCl extended-release tablets (generic)	X		X				

SNRI – Serotonin norepinephrine reuptake inhibitor; MDD – Major depressive disorder; GAD – Generalized anxiety disorder; SAD – Social anxiety disorder; DPN – Diabetic peripheral neuropathy; ^ Efficacy studied in patients ≥ 7 years of age with GAD; * Approved for use in patients ≥ 13 years of age; HCl – Hydrochloride

Automation: A patient with a history of one Step 1 Product (Standard Criteria) or two Step 1 Products (High Impact Criteria) within the 130-day look-back period is excluded from Step Therapy. Patients > 18 years of age are targeted in this Step Therapy program.

Step 1: generic bupropion extended-release tablets, generic bupropion sustained-release tablets, generic citalopram oral solution, generic citalopram tablets, generic duloxetine delayed-release (20 mg, 30 mg, 60 mg) capsules, generic escitalopram tablets, generic fluoxetine immediate-release capsules, generic fluoxetine oral solution, generic fluvoxamine immediate-release tablets, generic paroxetine HCl immediate-release tablets, generic sertraline oral solution, generic sertraline tablets, generic venlafaxine extended-release capsules, generic venlafaxine immediate-release tablets

Step 2: Aplenzin, Auvelity, Brisdelle, Bupropion XL tablets (authorized generics to Forfivo XL), Celexa, Citalopram capsules (brand), Cymbalta, Desvenlafaxine extended-release tablets (brand), generic desvenlafaxine succinate extended-release tablets, generic duloxetine 40 mg delayed-release capsules, Drizalma Sprinkle, Effexor XR, generic escitalopram oral solution, Fetzima, generic fluoxetine delayed-release 90 mg capsule, generic fluoxetine immediate-release tablets, generic fluvoxamine extended-release capsules, Forfivo XL, Lexapro, Paxil, Paxil CR, generic paroxetine HCl controlled-release (CR)/extended-release (ER) tablets, generic paroxetine HCl oral suspension, generic paroxetine mesylate capsules, Pexeva, Pristiq, Prozac, Sarafem, Savella, Sertraline capsules (brand), Trintellix, Venlafaxine besylate extended-release tablets (brand), generic venlafaxine HCl extended-release tablets, generic vilazodone hydrochloride tablets, Viibryd, Wellbutrin SR, Wellbutrin XL, Zoloft

STANDARD CRITERIA

1. If the patient has tried one Step 1 Product, approve a Step 2 Product.

2. If the patient is currently taking or has taken Desvenlafaxine extended-release tablets (brand product), desvenlafaxine succinate extended-release tablets (Pristiq or generics), Fetzima, Pexeva, vilazodone hydrochloride tablets (Viibryd or generics), or Trintellix at any time in the past and discontinued its use, approve the Product that they have used.

3. If the patient cannot swallow or has difficulty swallowing tablets or capsules, approve generic escitalopram oral solution or generic paroxetine HCl oral suspension.

4. If the patient has suicidal ideation, approve Desvenlafaxine extended-release tablets (brand product), desvenlafaxine succinate extended-release tablets (Pristiq or generics), Fetzima, Pexeva, vilazodone hydrochloride tablets (Viibryd or generics), or Trintellix.

HIGH IMPACT CRITERIA

1. If the patient has tried two Step 1 Products, approve a Step 2 Product.

2. If the patient is currently taking or has taken Desvenlafaxine extended-release tablets (brand product), desvenlafaxine succinate extended-release tablets (Pristiq or generics), Fetzima, Pexeva, vilazodone hydrochloride tablets (Viibryd or generics), or Trintellix at any time in the past and discontinued its use, approve the Product that they have used.

3. If the patient cannot swallow or has difficulty swallowing tablets or capsules, approve generic escitalopram oral solution or generic paroxetine HCl oral suspension.

4. If the patient has suicidal ideation, approve Desvenlafaxine extended-release tablets (brand product), desvenlafaxine succinate extended-release tablets (Pristiq or generics), Fetzima, Pexeva, vilazodone hydrochloride tablets (Viibryd or generics), or Trintellix.

Proton Pump Inhibitors (PPI) [Generic] Step Therapy Program

Proton Pump Inhibitor	Product	Manufacturer
Dexlansoprazole	Dexilant™ delayed-release capsules, generic	Takeda
Esomeprazole	Nexium® delayed-release capsules, generic	AstraZeneca
	Nexium® delayed-release granules for oral suspension, generic	
	Esomeprazole strontium delayed-release capsules	ParaPRO
Lansoprazole	Prevacid® delayed-release capsules, generic	Takeda
	Prevacid® SoluTab™ delayed-release orally disintegrating tablets, generic	
	Prevacid® 24HR delayed-release capsules, generic	GSK
Omeprazole	Omeprazole delayed-release capsules, generic only	Generics only
	Prilosec® delayed-release granules for oral suspension	AstraZeneca
	Prilosec OTC® delayed-release tablets, generic	Procter & Gamble
Omeprazole/ sodium bicarbonate	Zegerid® capsules, generic	Salix
	Zegerid® powder for oral suspension, generic	Procter & Gamble
	Zegerid OTC® capsules, generic	Bayer
Pantoprazole	Protonix® delayed-release tablets, generic	Wyeth
	Protonix® delayed-release oral suspension, generic	
Rabeprazole	Aciphex® delayed-release tablets, generic	Eisai
	Aciphex® Sprinkle™ delayed-release capsules	

Automation: A patient with a history of one Step 1 Product or Nexium 24HR (OTC) within the 130-day look-back period is excluded from Step Therapy.
Note: Automation is NOT in place for Step 2 Zegerid, Zegerid OTC, and generic omeprazole/sodium bicarbonate products (Rx/OTC).

Step 1: Generic esomeprazole delayed-release capsules, generic lansoprazole delayed-release capsules (Rx and OTC), generic omeprazole delayed-release capsules and tablets (Rx and OTC), generic pantoprazole delayed-release tablets, generic rabeprazole delayed-release tablets

Step 2: Aciphex, Aciphex Sprinkle, Dexilant, generic dexlansoprazole capsules, generic esomeprazole delayed-release granules for oral suspension, esomeprazole strontium delayed-release capsules, generic lansoprazole orally disintegrating tablets, Konvomep, Nexium, Prevacid, Prevacid 24HR, Prevacid SoluTab, Prilosec (Rx and OTC), Protonix, generic pantoprazole granules, Voquezna, Zegerid, Zegerid OTC, generic omeprazole/sodium bicarbonate capsules (Rx and OTC)

CRITERIA

4. If the patient requires administration via a feeding tube and has tried a Step 1 Product under the supervision of a physician, approve a Step 2 Product (except Zegerid, Zegerid OTC, and generic omeprazole/sodium bicarbonate capsules [Rx and OTC]).
Note: A trial of a generic OTC PPI would qualify.

5. If the patient has tried a Step 1 Product under the supervision of a physician, approve a Step 2 Product (except Zegerid, Zegerid OTC, and generic omeprazole/sodium bicarbonate capsules [Rx and OTC]).
Note: A trial of a generic OTC PPI would qualify, if OTC PPIs are a covered benefit and the patient was using it for at least 14 days.

6. If the patient is < 1 year of age, approve generic esomeprazole delayed-release granules for oral suspension (packets), Nexium delayed-release granules for oral suspension (packets), or Prilosec delayed-release granules for oral suspension (packets).

7. If the requested product is Zegerid, Zegerid OTC, or generic omeprazole/sodium bicarbonate capsules (Rx or OTC), approve if the patient has tried five generic PPIs (i.e., esomeprazole, lansoprazole [Rx or OTC], omeprazole [Rx or OTC], pantoprazole, AND rabeprazole).
Note: A trial of a generic OTC PPI would qualify, if OTC PPIs are a covered benefit and the patient was using it for at least 14 days.

8. No other exceptions are recommended.

Enhanced HMG-CoA Reductase Inhibitor (HMG) *Lipitor Non-Formulary* Step Therapy Program

POLICY: Hydroxy-methylglutaryl-coenzyme A Reductase Inhibitors Step Therapy Policy

* Altoprev® (lovastatin extended-release tablets – Covis)
* Atorvastatin and ezetimibe tablets (generic only)
* Caduet® (atorvastatin/amlodipine tablets – Pfizer, generic)
* Crestor® (rosuvastatin tablets – AstraZeneca, generic)
* Ezallor Sprinkle™ (rosuvastatin capsules – Sun)
* Flolipid® (simvastatin oral suspension – Salerno/Rosemont)
* Fluvastatin capsules (generic only)
* Lescol® XL (fluvastatin extended-release tablets – Novartis, generic)
* Lipitor® (atorvastatin tablets – Pfizer, generic)
* Livalo® (pitavastatin tablets – Lily/Kowa)
* Mevacor® (lovastatin tablets – generic)
* Pravachol® (pravastatin tablets – Bristol-Myers Squibb, generic)
* Roszet® (rosuvastatin andezetimibe tablets – Althera Pharmaceuticals)
* Rosuvastatin and ezetimibe tablets – SCOV3 LLC
* Vytorin® (ezetimibe/simvastatin tablets – Organon, generic)
* Zocor® (simvastatin tablets – Organon, generic)
* Zypitamag® (pitavastatin magnesium tablets – Medicare)

Automation: A patient with a history of one Step 1 Product within the 130-day look-back period is excluded from Step Therapy.

Step 1: atorvastatin, atorvastatin/amlodipine, ezetimibe/simvastatin, fluvastatin, fluvastatin extended-release, lovastatin, pravastatin, pitavastatin, rosuvastatin, simvastatin

Step 2: Altoprev, Atorvaliq, Caduet, Crestor, Ezallor Sprinkle, Flolipid, Lescol XL, Lipitor, Livalo, Pravachol, ezetimibe and rosuvastatin (brand product), Roszet, Vytorin, Zocor, Zypitamag

CRITERIA

9. If the patient has tried one Step 1 Product, approve a Step 2 Product.

10. If the patient cannot swallow or has difficulty swallowing tablets or capsules, approve Flolipid or Ezallor Sprinkle.

11. No other exceptions are recommended.

Sodium Glucose Co-Transporter-2 (SGLT-2) Inhibitors Step Therapy Program

POLICY: Diabetes – Sodium Glucose Co-Transporter-2 Inhibitors Step Therapy Policy

* Farxiga® (dapagliflozin tablets – Bristol-Myers Squibb)
    * Invokana® (canagliflozin tablets – Janssen)
    * Invokamet® (canagliflozin and metformin hydrochloride tablets – Janssen)
* Invokamet® XR (canagliflozin and metformin hydrochloride extended-release tablets – Janssen)
* Jardiance® (empagliflozin tablets – Boehringer Ingelheim/ Lilly)
* Segluromet® (ertugliflozin and metformin tablets – Merck)
* Steglatro® (ertugliflozin tablets – Merck)
* Synjardy® (empagliflozin/metformin hydrochloride tablets – Boehringer Ingleheim/ Lilly)
* Synjardy® XR (empagliflozin/metformin extended-release tablets – Boehringer Ingleheim/Lilly)
* Xigduo® XR (dapagliflozin/metformin extended-release tablets – Bristol-Meyers Squibb)

Automation: The following automation is applied in this policy:

- **Requests for a Step 2 Product:** A patient with a history of one of the following within the 130-day look-back period is excluded from Step Therapy:
    - One Step 1 Product; OR
    - One of the following metformin-containing products: Glumetza ER, Riomet, metformin oral solution, Riomet ER, metformin extended-release (generics to Fortamet ER and Glumetza ER), glyburide/metformin, glipizide/metformin, Actoplus Met, pioglitazone/metformin, Kazano, alogliptin/metformin, Jentadueto, Jentadueto XR, Kombiglyze XR, saxagliptin/metformin extended-release, Janumet, Janumet XR; OR
    - One Step 2 Product; OR
    - One Step 3 Product.
- **Requests for a Step 3 Product:** A patient with a history of one Step 2 Product within the 130-day look-back period is excluded from Step Therapy.

Step 1: generic metformin, generic metformin-extended release (generic to Glucophage XR only)

Step 2: Farxiga, Jardiance, Synjardy, Synjardy XR, Xigduo XR

Step 3: Brenzavvy, Invokana, Invokamet, Invokamet XR, dapagliflozin (authorized generic to Farxiga), dapagliflozin/metformin extended-release (authorized generic to Xigduo XR), Segluromet, Steglatro

CRITERIA

Step 2 Products

1. If the patient has tried one Step 1 Product, approve a Step 2 Product.
   Note: A trial of one of the following metformin-containing products also satisfies the requirement: Fortamet ER (obsolete), Glucophage (obsolete), Glucophage XR (obsolete), Glumetza ER, Riomet, metformin oral solution, Riomet ER, metformin extended-release (generics to Fortamet ER and Glumetza ER), glyburide/metformin, glipizide/metformin, Actoplus Met, pioglitazone/metformin, Actoplus Met XR (obsolete), repaglinide/metformin (obsolete), Kazano, alogliptin/metformin, Jentadueto, Jentadueto XR, Kombiglyze XR, saxagliptin/metformin extended-release, Janumet, Janumet XR.

2. If the patient has tried one Step 2 Product, approve the requested Step 2 Product.

3. If the patient has tried one Step 3 Product, approve the requested Step 2 Product.

4. If the patient will be initiating dual therapy with metformin AND Farxiga or Jardiance approve Farxiga or Jardiance.

5. If the patient has a contraindication to metformin, according to the prescriber, approve Farxiga, or Jardiance.
   Note: Examples of contraindications to metformin include acute or chronic metabolic acidosis, including diabetic ketoacidosis.

6. If the patient has heart failure, approve Farxiga or Jardiance.

7. If the patient has chronic kidney disease, approve Farxiga or Jardiance.

8. If the patient has atherosclerotic cardiovascular disease or, according to the prescriber, the patient has at least two risk factors for cardiovascular disease, approve Farxiga or Jardiance.

9. No other exceptions are recommended.

Step 3 Products

1. If the patient has tried one Step 2 Product, approve a Step 3 Product.
Note: A trial of a Step 1 Product is required prior to a Step 2 Product, unless exception criteria are met.

2. No other exceptions are recommended.

Diabetes – Sodium Glucose Co-Transporter-2 and Dipeptidyl Peptidase-4 Inhibitors Step Therapy Policy

POLICY: Diabetes – Sodium Glucose Co-Transporter-2 and Dipeptidyl Peptidase-4 Inhibitors Step Therapy Policy

- Glyxambi® (empagliflozin and linagliptin tablets – Boehringer Ingelheim)
- Qtern® (dapagliflozin and saxagliptin tablets – AstraZeneca)
- Steglujan® (ertugliflozin and sitagliptin tablets – Merck)
- Trijardy® XR (empagliflozin, linagliptin, and metformin extended-release tablets – Boehringer Ingelheim)

Automation: A patient with a history of one of the following within the 130-day look-back period is excluded from Step Therapy:

- One Step 1 Product; OR
- One of the following metformin-containing products: Glumetza ER, Riomet, metformin oral solution, Riomet ER, metformin extended-release (generics to Fortamet ER and Glumetza ER), metformin/glyburide, metformin/glipizide, Actoplus Met, pioglitazone/metformin, Janumet, sitagliptin/metformin (authorized generic), Janumet XR, Kombiglyze XR, saxagliptin/metformin extended-release, Jentadueto, Jentadueto XR, Kazano, aloglitpin/metformin (authorized generic to Kazano), Synjardy, Synjardy XR, Xigduo XR, dapagliflozin/metformin extended-release (authorized generic to Xigduo XR), Invokamet, Invokamet XR, Segluromet; OR
- One of the following DPP-4 inhibitor products: Januvia, Nesina, alogliptin, Onglyza, saxagliptin, Tradjenta, Oseni, alogliptin/pioglitazone, Zituvio; OR
- One SGLT-2 inhibitor (Brenzavvy, Farxiga, dapagliflozin [authorized generic to Farxiga], Invokana, Jardiance, Steglatro).

Step 1: generic metformin, generic metformin extended-release (generic to Glucophage XR only)

Step 2: Glyxambi, Qtern, Steglujan, Trijardy XR

CRITERIA

1. If the patient has tried one Step 1 Product, approve a Step 2 Product.
2. Note: A trial of one of the following metformin-containing products also satisfies the requirement: Glucophage (obsolete), Glucophage XR (obsolete), Glumetza ER, Fortamet ER (obsolete), Riomet, metformin oral solution, Riomet ER, metformin extended-release (generics to Fortamet ER and Glumetza ER), metformin/glyburide, metformin/glipizide, Actoplus Met, pioglitazone/metformin, Actoplus Met XR (obsolete), Janumet, sitagliptin/metformin (authorized generic), Janumet XR, repaglinide/metformin (obsolete), Kombiglyze XR, saxagliptin/metformin extended-release, Jentadueto, Jentadueto XR, Kazano, aloglitpin/metformin (authorized generic to Kazano), Synjardy, Synjardy XR, Xigduo XR, dapagliflozin/metformin extended-release (authorized generic to Xigduo XR), Invokamet, Invokamet XR, Segluromet.
3. If the patient has tried a DPP-4 inhibitor, a DPP-4 inhibitor-containing product, or an SGLT-2 inhibitor, other than Glyxambi, Qtern, Steglujan, or Trijardy XR, approve a Step 2 Product.
   Note: Examples of DPP-4 inhibitors include but are not limited to Januvia, Nesina, alogliptin (authorized generic to Nesina), Onglyza, saxagliptin, Tradjenta, Zituvio, and sitagliptin (authorized generic to Zituvio). Examples of DPP-4 inhibitor-containing products include but are not limited to Oseni and

alogliptin/pioglitazone (authorized generic to Oseni). Examples of SGLT-2 inhibitors include but are not limited to Brenzavvy, Farxiga, dapagliflozin (authorized generic to Farxiga), Invokana, Jardiance, Steglatro.

4. If the patient has tried a DPP-4 inhibitor, DPP-4 inhibitor-containing product, or an SGLT-2 inhibitor, other than Glyxambi, Qtern, Steglujan, or Trijardy XR, approve a Step 2 Product.
Note: Examples of DPP-4 inhibitors include but are not limited to Januvia, Nesina, alogliptin, Onglyza, and Tradjenta. Examples of DPP-4 inhibitor-containing products include but are not limited to Oseni and alogliptin/pioglitazone. Examples of SGLT-2 inhibitors include but are not limited to Farxiga, Invokana, Jardiance, Steglatro.

5. If the patient has a contraindication to metformin, according to the prescriber, approve Glyxambi, Qtern, or Steglujan.
Note: Examples of contraindications to metformin include acute or chronic metabolic acidosis, including diabetic ketoacidosis.

6. No other exceptions are recommended.
Note: Examples of contraindications to metformin include acute or chronic metabolic acidosis, including diabetic ketoacidosis.

7. No other exceptions are recommended.

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Revision Date	Content Revised (Yes/No)	Contributors	Review/Revision Notes
1/23/18	No	Catherine Sanders, MD; Robert Sterling, MD	Annual review
4/1/18	Yes	Catherine Sanders, MD	Update to Angiotensin Receptor Blocker (ARB) StepTherapy Program
7/24/18	No	Catherine Sanders, MD; Robert Sterling, MD	Annual review

10/23/18	Yes	Robert Sterling, MD	Adopted the Diabetes Step Therapy Policies: • Diabetes – Dipeptidyl Peptidase-4 (DPP-4) InhibitorsPreferred StepTherapy • Diabetes- Glucagon-Like Peptide-1 (GLP-1) AgonistPreferred StepTherapy • Diabetes-Insulin (Other) Preferred Step Therapy • Diabetes-Insulin (Rapid Acting) Preferred StepTherapy
1/22/19	No	Catherine Sanders, MD; Robert Sterling, MD	Annual review
4/23/19	Yes	Catherine Sanders, MD; Robert Sterling, MD	Updated the following: • NSAIDS • Diabetes- Glucagon-Like Peptide-1 (GLP-1)Agonist PreferredStep Therapy • Added Market Events Program
7/23/19	Yes	Howard Taekman, MD;Robert Sterling, MD	Update to Tetracyclines (oral) Step Therapy Program
10/30/19	Yes	Howard Taekman, MD;Robert Sterling, MD	Brand Rhinocort removed from Step 2; generic triamcinolone and genericbudesonide removed from Step 1 (products obsolete). Moved flunisolide nasal spray and mometasone furoate nasal spray from Step 1to Step 2. Added criteria to provide authorization for mometasone furoate nasal spray,Nasonex, or Veramyst for patients < 4 years of age. Deleted Market Events Program
02/18/20	Yes	Howard Taekman, MD;Robert Sterling, MD	Effective 1/1/2020: Abbott test strips, except FreestylePrecision Neo, areStep 1 for both Basic and National Preferred Formularies. Freestyle Precision Neo test strips are Step 2 for both Basic and National PreferredFormularies. Rybelsus added to Step 1 (Basic/National PreferredFormularies) and toStep 2 (High Performance Formulary). Effective 1/1/2020: ReliOn Novolin R, ReliOn Novolin N, and ReliOnNovolin 70/30 products addedto policy (Step 2) Authorized generics to NovoLog (insulin aspart FlexPen, PenFill catridge,and vial) and NovoLog 70/30 mix (insulin aspart protamine FlexPen, vial)added to Step 2.
04/28/20	Yes	Howard Taekman, MD;Robert Sterling, MD	Generic ramelteon tablets were moved from Step 2 toStep 1. Additionally, generic doxepin 3 mg and 6 mg tabletswere added to Step 2. Added generics to Dymista to Step 2. RemovedVeramyst from Step 2 (productobsolete). Removed Ocudox Convenience Kit from Step 1 –obsolete Generic esomeprazole delayed release granules for oralsuspension was added to Step 2 in the policy. The addition of generic esomeprazole delayedrelease granules for oral suspension (packets) for criteria of patient is < 1 year of age was put in as an option. 4/7/2020: Addition of “capsules” to generic paroxetinemesylate listed in Step2 medications.
06/18/20	Yes	Howard Taekman, MD;Robert Sterling, MD	Update to the SGLT-2 Step Therapy Program: Addedthe following: If the patient has a contraindication to metformin,according to the prescriber, then authorization for Farxiga, Invokana, Jardiance, or Steglatro may be given. (Note:Examples of contraindications to metformin include acute or chronic

			metabolicacidosis,including diabetic ketoacidosis). For patients with heart failure with reduced ejection fraction, authorization for Farxiga may begiven.
10/27/20	Yes	Howard Taekman, MD;Robert Sterling, MD	Ketoprofen IR (Ketoprofen 25 mg capsules) moved toStep 2a. Generic to Vimovo (naproxen and esomeprazoledelayed-releasetablets) added to Step 2b. Clarification was made to note that exception criteria are applied to bothgeneric celecoxib requests, as wellas to brand Celebrex requests (brand Celebrex continues to require a trial of generic celecoxib). Ketoprofen IR 25 mg removed from Step 1 (ketoprofenIR 50 mg and 75 mgremain in Step 1). Additionally, the following Step 1 drugs were missing from the policy and have been added: ketorolac (tablets), piroxicam. Exceptions for familial adenomatous polyposis, aspirin/NSAID allergy, and aspirin- or NSAID-sensitive asthma removed from policy. 11/05/2020: Removed Ocudox Convenience Kit fromStep 1 – obsolete Added several generic doxycycline products to Step 2.Clarified the Step 1and Step 2 generic doxycycline products: 10/05/2020: Clarified that the doxycycline hyclate 50 mg, 75 mg, 80 mg, 100mg, 150 mg, 200 mg tablets aredelayed-release doxycycline hyclate -- doxycycline hyclate delayed-release 50 mg, 75 mg, 80 mg, 100 mg, 150 mg, 200 mg tablets Generic pantoprazole granules were added to Step 2 inthe policy.
2/2/21	Yes	Howard Taekman, MD;Robert Sterling, MD	Teveten and Teveten HCT were removed from Step 2 as they are no longer available. Regarding the criteriathat addresses if a patient has been recently hospitalized and discharged within the last 30 days fora cardiovascular event, the word “recently” was removed since this timeframe is already defined in thecriteria. Examples of a cardiovascular event were moved fromthe criteria to a Note. Generic lansoprazole orally disintegrating tablets werechanged from a Step 1 product to a Step 2 product. “Prescribing physician” updated to “prescriber” incriteria. Exception criteria regarding cardiovascular disease removed from policy; Step 1 products are now also indicated in this setting (Ozempic/Trulicity). Renal impairment exception removed; products areavailable in Step 1which can be used in renal impairment, including ESRD. Tradjenta, Jentadueto, and Jentadueto XR moved fromStep 1 to Step 2. Novolin R FlexPens, Relion Novolin R FlexPens, Novolin N FlexPens, and Relion Novolin N FlexPensadded to Step 2. An exception criterion was added toapprove Novolin R FlexPens or Relion Novolin R FlexPens ifa patient is visually impaired, disabled (unable to draw up dose because of arthritis or otherwise physically disabled), or has coordination issues. Product list updated to reflect availability. Lyumjev products (U-100 vials,U-100 KwikPen, U-200 KwikPen) added to Step 1. Insulin lispro Jr. KwikPensand Insulin lispro 75/25 mix KwikPens added to Step 2.

4/1/21	Yes	Howard Taekman, MD;Robert Sterling, MD	Viibryd removed per 4/1/21 NPF exclusion
5/4/21	Yes	Howard Taekman, MD; RobertSterling, MD	Meloxicam capsules (generic to Vivlodex) added to Step 2a. Clarified that the Step 1a meloxicam products are the meloxicam tablets. Clarification was added to note that the following products are Step 2a: diclofenac epolamine 1.3% patch, Relafen, and Relafen DS. The following obsolete products were removed from the policy: Anaprox, Ansaid, Klofensaid II, Pennsaid 1.5%, Ponstel. For the criterion addressing patients with chronic musculoskeletal pain and increased risk of NSAID-associated toxicity, examplesof NSAID-associated toxicity were moved to a note. To the criterion addressingswallowing difficulty, diclofenac epolamine 1.3% patch was added to the list of approvable medications and Klofensaid II was removed (obsolete). To the criterion addressing hand or knee osteoarthritis, Klofensaid II was removed from the list of approvable medications (obsolete). Metformin oral solution added to Step 1. Additionally, the policy statement was clarified to note that all components of automation involve a 130-day look-back period. Clarified that in Step 1, doxycycline hyclate tablets include the 20 mg strength; doxycycline monohydrate/Mondoxyne capsules include the 75 mg strength [thiswas previously Step 2]; and all strengths of doxycycline monohydrate suspension are included. There are no new Step 2 products; this revision clarified the strengths of the Step 2 products. No criteria changes. Step 1: Added doxycycline monohydrate capsules/tablets 50 mg, 75 mg, 100 mg, and 150 mg (tablet only) Step 2: Added Doxycycline IR-ER 40 mg capsules (Authorized generic); Solodyn ER tablets (generic). Removed desvenlafaxine fumerate from the policy because it has been discontinued. Added Drizalma Sprinkle as a Step 2 Product. Removed obsolete fluoxetine 60 mg tablets (brand product) from Step 2. No criteria changes.
8/3/21	Yes	Howard Taekman, MD; Robert Sterling, MD	Clarification was added to note that the following products are Step 2a: diclofenac epolamine 1.3% patch, Relafen, and Relafen DS. The following obsolete products were removed from the policy: Anaprox, Ansaid, Klofensaid II, Pennsaid 1.5%, Ponstel. For the criterion addressing patients with chronic musculoskeletal pain and increased risk of NSAID-associated toxicity, examples of NSAID-associated toxicity were moved to a note. To the criterion addressing swallowing difficulty, diclofenac epolamine 1.3% patch was added to the list of approvable medications and Klofensaid II was removed (obsolete). To the criterion addressing hand or knee osteoarthritis, Klofensaid II was removed from the list of approvable medications (obsolete). Criteria: Clarified to note that if a patient has tried any Step 2 Product, the request for any other Step 2 Product will be approved. Ximino XR capsules: Authorized generics of Ximino XR capsules were added to Step 2. Removed desvenlafaxine fumerate from the policy because it has been discontinued. Added Drizalma Sprinkle as a Step 2 Product. Avandamet: Avandamet was removed from Step 1 (obsolete). Criteria: Exception criteria were clarified to note that if a patient has tried any Step 2 Product, the request for any other Step 2 Product will be approved. The phrase “single-entity sodium glucose co-transporter-2 inhibitor” was clarified to mean Farxiga, Invokana, Jardiance, or Steglatro. An exception was added to approve Farxiga in a patient with chronic kidney disease, based on updated FDA labeling.

11/02/21	Yes	Howard Taekman, MD; Robert Sterling, MD	Ibuprofen/Famotidine: Ibuprofen/famotidine tablets (generic to Duexis) was added to Step 2c. Ximino XR capsules: Authorized generics of Ximino XR capsules were added to Step 2. No criteria changes. Criteria: In the exception criterion regarding a patient with heart failure with reduced ejection fraction, Jardiance was added to the list of approvable medications.
2/1/22	Yes	Howard Taekman, MD; Robert Sterling, MD	Teveten, Teveten HCT: Teveten and Teveten HCT were removed from Step 2 as they are no longer available. Regarding the criteria that addresses if a patient has been recently hospitalized and discharged within the last 30 days for a cardiovascular event, the word "recently" was removed since this timeframe is already defined in the criteria. Examples of a cardiovascular event were moved from the criteria to a Note Changed "addiction to controlled substances" to "substance use disorder" in the criteria. Zercapli (sertraline capsules - Almatica/Viking): Added to Step 2. No criteria changes. Rosuvastatin and ezetimibe tablets (branded product by SCOV3 LLC): Added as a Step 2 Product. No criteria changes. Invokana, Invokamet, and Invokamet XR: These medications were removed from Step 2 and added to Step 3. A patient who has tried one Step 2 Product may receive a Step 3 Product. Criteria: Exceptions to approve Invokana if initiated concomitantly with metformin or if the patient has a metformin contraindication were removed. A patient is still directed to try a Step 2 Product in these cases. Tanzeum: Tanzeum was removed from Step 2 (obsolete). Victoza: Exception criterion for Victoza for a patient < 18 years of age was removed. Apidra, Fiasp, insulin aspart, and NovoLog: Exceptions added to approve Apidra, Fiasp, insulin aspart (not protamine formulations), or NovoLog (not mix formulations) under one of the following circumstances: the patient has tried Admelog or insulin lispro (not mix formulations); OR the patient is using an insulin pump that is not compatible with a Step 1 Product. Insulin aspart protamine and NovoLog 70/30 Mix: An exception was added that if the patient has tried insulin lispro 75/25 mix, approval is authorized for NovoLog 70/30 mix or insulin aspart protamine.
5/3/22	Yes	Howard Taekman, MD; Robert Sterling, MD	Cataflam: The policy was clarified to note that Cataflam is a Step 1a product. Previously, this was listed in Step 2a. Diclofenac potassium: Clarification was added to note that diclofenac potassium 25 mg tablets are Step 2a; diclofenac potassium 50 mg remains Step 1a. Lofena: Lofena was added to Step 2a. Motrin: Brand Motrin was removed from Step 2a; this product has been obsolete > 3 years. Sprix: Clarified that authorized generic ketorolac nasal spray is also Step 2a. Tivorbex: Clarified that authorized generic indomethacin 20 mg capsule is also Step 2a. Tolmetin: Clarified that the Step 1a strength is 200 mg. Zorvolex: Clarified that authorized generic diclofenac 35 mg capsule is also Step 2a. Removed Products: Brand Prozac Weekly and brand Luvox CR were removed from Step 1 (obsolete ≥ 3 years). Brand Venlafaxine HCl extended-release tablets were removed from Step 2 (obsolete ≥ 3 years). No criteria changes. Removed Products: Brand Prozac Weekly and brand Luvox CR were removed from Step 2 (obsolete ≥ 3 years). No criteria changes.

			Citalopram capsules: Citalopram capsules were added to Step 1. Criteria: Criteria were updated to add that a patient who has previously tried a Step 3 Product (Invokana, Invokamet, or Invokamet XR) may receive a Step 2 Product. Automation: Automation was updated such that a claim for a Step 2 Product will adjudicate if the patient has a history of one Step 1 Product, one Step 2 Product, or one Step 3 Product in the 130-day look-back period; previously, the automation only involved look-back for a Step 1 Product or a Step 2 Product. Criteria: An exception was added for Jardiance in heart failure with preserved ejection fraction based on FDA labeling.
8/2/22	Yes	Howard Taekman, MD; Robert Sterling, MD	Diclofenac sodium 2% topical solution: This product was added to Step 2a. Criteria: In the exception regarding difficulty swallowing, it was noted that the same exception which applies to Sprix also applies to the authorized generic ketorolac nasal spray. Additionally, the same exceptions which apply to Pennsaid 2% also apply to generic diclofenac sodium 2% topical solution. Step 1 Products: The Step 1 Products were revised such that only metformin and metformin extended-release (generic to Glucophage XR only) are listed in Step 1. A Note was added that the following metformin-containing products also satisfy the requirement for a Step 1 trial (previously, these products were also listed in Step 1): Fortamet, Glucophage, Glucophage XR, Glumetza, Riomet, metformin oral solution, Riomet ER, metformin extended-release (generics to Fortamet and Glumetza), glyburide/metformin, glipizide/metformin, Actoplus Met, pioglitazone/metformin, Actoplus Met XR, repaglinide/metformin, Invokamet, Invokamet XR, Synjardy, Synjardy XR, Xigduo XR, Segluromet. Of note, Glucovance was removed from this list (obsolete). Quviviq: Quviviq was added to the list of Step 2 medications. Removed brand Nasonex from Step 2 as this product is now only available over-the-counter. Also removed Nasonex from the override criteria for a patient < 4 years of age. Dexlansoprazole capsules: Generic dexlansoprazole capsules were added to the policy as a Step 2 product. Criteria: An exception was added for a patient who requires administration via a feeding tube to obtain a Step 2 Product if the patient has tried one Step 1 Product. A Note for this exception allows for an over-the-counter product to count as a trial. Ezallor Sprinkle: Exceptions were added for Ezallor Sprinkle – if the patient cannot swallow or has difficulty swallowing tablets or capsules. It was also clarified that the name of Ezallor contains the descriptor of “Sprinkle”. Step 1 Products: The Step 1 Products were revised such that only metformin and metformin extended-release (generic to Glucophage XR only) are listed in Step 1. A Note was added that the following metformin-containing products also satisfy the requirement for a Step 1 trial (previously, these products were also listed in Step 1): Fortamet, Glucophage, Glucophage XR, Glumetza, Riomet, metformin oral solution, Riomet ER, metformin extended-release (generics to Fortamet and Glumetza), glyburide/metformin, glipizide/metformin, Actoplus Met, pioglitazone/metformin, Actoplus Met XR, repaglinide/metformin, Kazano, alogliptin/metformin, Jentadueto, Jentadueto XR, Kombiglyze XR, Janumet, Janumet XR. Of note, Glucovance was removed from this list (obsolete). Step 1 Products: The Step 1 Products were revised such that only metformin and metformin extended-release (generic to Glucophage XR only) are listed in Step 1. A Note was added that the following metformin-containing products also satisfy the requirement for a Step 1 trial (previously, these products were also listed in Step 1): Glucophage, Glucophage XR, Glumetza, Fortamet, Riomet, metformin oral solution, Riomet ER, metformin extended-release (generics to Fortamet and Glumetza), metformin/glyburide, metformin/glipizide, Actoplus Met, pioglitazone/metformin, Actoplus Met XR, Janumet, Janumet XR, repaglinide/metformin, Kombiglyze XR, Jentadueto, Jentadueto XR, Kazano, aloglitpin/metformin, Synjardy, Synjardy XR, Xigduo XR, Invokamet, Invokamet XR, Segluromet. Of note, Glucovance was removed from this list (obsolete).

11/01/22	Yes	Howard Taekman, MD; Robert Sterling, MD	Meloxicam suspension: Meloxicam suspension was added to Step 2a. In exception criteria, it was added that meloxicam suspension can be approved if the patient has tried ibuprofen suspension. Automation: The existing automation was updated to change "Xarelto (rivaroxaban tablets)" to "Xarelto (rivaroxaban tablets and oral suspension)" to reflect the availability of a new dosage form. 1 Products: Cataflam and fenoprofen were added to the Step 1 Products Criteria: The criterion regarding a patient currently taking Xarelto (rivaroxaban tablets) was updated to also include Xarelto oral suspension. Ryaltris was added to Step 2. Doryx MPC 60 mg tablets: Branded Doryx MPC 60 mg tablets were added to Step 2. Trintellix: Throughout the policy, the note "(formerly Brintellix)" was removed. The brand name was changed from Brintellix to Trintellix in 2016. Generic vilazodone tablets: Generic vilazodone tablets were added to the policy as Step 2. Generic fluoxetine delayed-release capsules: Generic fluoxetine delayed-release capsules were moved to Step 2. Generic escitalopram oral solution: Generic escitalopram oral solution was moved to Step 2. Criterion was added to the Standard and High Impact Criteria to approve for patients who cannot swallow or have difficulty swallowing tablets or capsules. Generic paroxetine oral suspension: Generic paroxetine oral suspension was moved to Step 2. Criterion was added to the Standard and High Impact Criteria to approve for patients who cannot swallow or have difficulty swallowing tablets or capsules. The following change is effective 01/01/2023: The header "Basic Formulary and National Preferred Formulary" was removed prior to the Step 1 and Step 2 product list; there is no longer reference to a specific formulary. Criteria: An exception was added that if the patient has atherosclerotic cardiovascular disease or, according to the prescriber, the patient has at least two risk factors for cardiovascular disease, approve Farxiga or Jardiance.
1/31/23	Yes	Howard Taekman, MD; Robert Sterling, MD	Added to the policy as a Step 2 product. No criteria changes. Venlafaxine besylate extended-release tablets were added as a Step 2 Product. No criteria changes. PIP Test Strips (manufactured by Medicore) were added to Step 2. Mounjaro was added to Step 1 for both the Basic/National Preferred Formularies and the High Performance Formulary. ReliOn NovoLog was added to Step 2. Criteria were updated such that the same exceptions are applied to ReliOn NovoLog as were already in place for NovoLog ReliOn NovoLog 70/30 Mix was added to Step 2. Criteria were updated such that the same exceptions are applied to ReliOn NovoLog 70/30 Mix as were already in place for NovoLog 70/30 Mix.
3/10/23	Yes	Howard Taekman, MD; Robert Sterling, MD	Auvelity: Added to the policy as a Step 2 product. No criteria changes. Venlafaxine besylate extended-release tablets were added as a Step 2 Product. No criteria changes. PIP Test Strips (manufactured by Medicore) were added to Step 2. Mounjaro was added to Step 1 for both the Basic/National Preferred Formularies and the High Performance Formulary.

5/2/23	Yes	Howard Taekman, MD; Robert Sterling, MD	Add Cambia, diclofenac potassium powder packet Auvelity: Added to the policy as a Step 2 product. No criteria changes. Venlafaxine besylate extended-release tablets were added as a Step 2 Product. No criteria changes. Citalopram capsules were moved from Step 1 to Step 2. Citalopram capsules were listed as generic; however, this is a brand product. Name changed from Zercapli to sertraline capsules. The approved brand name (Zercapli) was not utilized for this product. Atorvastatin and ezetimibe (generic product): Added as a Step 2 Product. PIP Test Strips (manufactured by Medicore) were added to Step 2. Humalog Tempo Pen and Lyumjev Tempo Pen were removed from Step 1, and added to Step 2.
8/1/23	Yes	Howard Taekman, MD; Robert Sterling, MD	The following products were removed from the automation (obsolete): Glucophage, Glucophage XR, repaglinide/metformin, Actoplus Met XR. Glumetza and Fortamet were clarified to be Glumetza ER and Fortamet ER. For patients requesting a Step 2 product, the note was updated to reflect that Glucophage, Glucophage XR, repaglinide/metformin, and Actoplus Met XR are obsolete (these still count towards a trial of a Step 1 product). Additionally Glumetza and Fortamet were clarified to be Glumetza ER and Fortamet ER. Savella no longer requires a trial of two Step 1 and/or Step 2 products; it now requires a trial of one Step 1 product. Therefore, the automation for all Step 2 products now states that a patient with a history of one Step 1 Product within the 130-day look-back period is excluded from Step Therapy. Savella no longer requires a trial of two Step 1 and/or Step 2 products; it now requires a trial of one Step 1 product. Therefore, the following criteria have been removed: If the patient has tried at least two Products from Step 1 and/or Step 2 (other than Savella), approve Savella; and if the patient is being treated for fibromyalgia (with or without depression) and the patient has tried duloxetine delayed-release capsules (brand or generic), approve Savella. Also, "(other than Savella)" was removed from the criterion stating if the patient has tried one Step 1 Product, approve a Step 2 Product. Konvomep oral suspension was added to the policy as a Step 2 product and is not captured in Automation. Konvomep was added to exception requiring a trial of five generic PPIs prior to approval. Added as a Step 2 Product. Exceptions are made if the patient cannot swallow or has difficulty swallowing tablets or capsules. PIP Test Strips (manufactured by Medicore) were added to Step 2. The following products were removed from the automation (obsolete): Glucophage, Glucophage XR, repaglinide/metformin, Actoplus Met XR. Glumetza and Fortamet were clarified to be Glumetza ER and Fortamet ER. Criteria Step 2 Products: For patients requesting a Step 2 product, the note was updated to reflect that Glucophage, Glucophage XR, repaglinide/metformin, and Actoplus Met XR are obsolete (these still count towards a trial of a Step 1 product). Additionally Glumetza and Fortamet were clarified to be Glumetza ER and Fortamet ER. For patients requesting a Step 2 product with heart failure with preserved ejection fraction, Farxiga was added to the agent approved. Previously only Jardiance was approved. For patients requesting a Step 2 product with chronic kidney disease, Jardiance was added to the agent approved. Previously, only Farxiga was approved. The following products were removed from the automation (obsolete): Glucophage, Glucophage XR, repaglinide/metformin, Actoplus Met XR. Glumetza and Fortamet were clarified to be Glumetza ER and Fortamet ER.

			For patients requesting a Step 2 product, the note was updated to reflect that Glucophage, Glucophage XR, repaglinide/metformin, and Actoplus Met XR are obsolete (these still count towards a trial of a Step 1 product). Additionally, Glumetza and Fortamet were clarified to be Glumetza ER and Fortamet ER. For patients who have tried a DPP-4 inhibitor, a DPP-4 inhibitor-containing product, or an SGLT-2 inhibitor, examples of these products were moved to a note.
11/07/23	Yes	Howard Taekman, MD; Robert Sterling, MD	Step 2 Products: Saxagliptin (generic to Onglyza) and saxagliptin/metformin extended-release (generic to Kombiglyze XR) were added to Step 2 products. Criteria: For patients initiating dual (combination) therapy with a single-entity DPP-4 inhibitor AND metformin, saxagliptin was added to the list of single-entity DPP-4 inhibitors to approve. Zolpidem capsule: Zolpidem capsule was added to the list of Step 2 medications. Automation: Saxagliptin/metformin extended-release (generic to Kombiglyze XR) was added to the list of metformin-containing products. Benzavvy was added to Step 3 Automation: Brenzavvy was added to automation for one sodium glucose co-transporter-2 inhibitor, saxagliptin (generic for Onglyza) was added to automation for one dipeptidyl peptidase-4 inhibitor, and saxaglptin/metformin extended-release (generic to Kombiglyze XR) was added to automation for one metformin-containing product.
02/13/24	Yes	Howard Taekman, MD; Robert Sterling, MD	Voquezna: Voquezna tablet was added to the Policy to Step 2. Pitavastatin (generic): Added as a Step 1 Product. There were no other changes to the criteria.
05/7/24	Yes	Howard Taekman, MD; Robert Sterling, MD	Added Indomethacin Oral. Added Zituvio to Step 2 Added Zituvio Added Tetracycline Tablets (All Strengths) to Step 2 Removed Effexor (immediate-release), Irenka, and Khedezla were removed from Step 2 (obsolete ≥ 3 years). Khedezla was removed from criteria because it is obsolete. Pitavastatin (generic): Added as a Step 1 Product. There were no other changes to the criteria. Added dapagliflozin (authorized generic to Farxiga) and dapagliflozin/metformin extended-release (authorized generic to Xigduo XR) were added to Step 3. dapagliflozin/metformin extended-release (authorized generic to Xigduo XR) was added to automation for one metformin-containing product. Dapagliflozin (authorized generic to Farxiga) was added to automation for one sodium-glucose co-transporter-2 (SGLT-2) inhibitor product.
08/6/24	Yes	Howard Taekman, MD; Robert Sterling, MD	Added Indomethacin Oral. Added dapaglifloxin/metformin extended-release. Remove Fortamet ER. Sitaglipin to step 2. Fortamet ER marked as obsolete Doxycycline IR-ER capsules added to Step 2 Fluvastatin capsules added; Brand Lescol removed Ezetimibe and atorvastatin tablets (generic product) and Lescol: Removed from Step 2 as these products are no longer available. Fortamet ER was removed from the list of metformin-containing products (obsolete). Added “Obsolete” to Fortamet ER For the new combined criterion, Farxiga or Jardiance is approved for a patient with heart failure. Noted that Fortamet ER is obsolete the note was updated to add sitagliptin (authorized generic to Zituvio).
11/5/24	Yes	Howard Taekman, MD; Robert Sterling, MD	The exception to approve Prexxartan if the patient cannot swallow or has difficulty swallowing tablets was changed to approve valsartan oral solution if the patient cannot swallow or has difficulty swallowing tablets. Step 2 Products: Sitagliptin/metformin (authorized generic) was added to Step 2 products. The following changes are effective 01/01/2025: Step 2 Products: Steglatro and Segluromet were removed (moved to Step 3).

			Step 3 Products: Steglatro and Segluromet were added (previously, Step 2). The following changes are effective 01/01/2025: Criteria for Step 2 Products: Steglatro was removed from the following criterion: In a patient initiating dual therapy with metformin AND Farxiga, Jardiance, or Steglatro, approve Farxiga, Jardiance, or Steglatro. The criterion continues to approve Farxiga or Jardiance in a patient initiating dual therapy with metformin and Farxiga or Jardiance. Steglatro was removed from the following criterion: In a patient with a contraindication to metformin, according to the prescriber, approve Farxiga, or Jardiance, or Steglatro. The criterion continues to approve Farxiga or Jardiance in a patient with a contraindication to metformin, according to the prescriber. Automation: Sitagliptin/metformin (authorized generic) was added to automation for one metformin-containing product. Criteria: For a patient requesting a Step 2 product, the note was updated to add sitagliptin/metformin (authorized generic) to the list of metformin-containing products