

VCHCP Step Therapy Policy

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Angiotensin Receptor Blocker (ARB) Step Therapy Program	1
Antidepressant Step Therapy Program – Bupropion	11
Branded Nonsteroidal Anti-Inflammatory Drug (NSAID) Step Therapy Program	3
Cyclooxygenase-2 (COX-2) Inhibitor Step Therapy Program.....	6
Diabetes – Dipeptidyl Peptidase-4 (DPP-4) Inhibitors Preferred Step Therapy	18
Diabetes – Glucagon-Like Peptide-1 (GLP-1) Agonists Preferred Step Therapy	18
Diabetes – Insulin (Other) Preferred Step Therapy.....	19
Diabetes – Insulin (Rapid-Acting) Preferred Step Therapy	20
Diabetic Test Strip Preferred Step Therapy Policy	16
Dipeptidyl Peptidase-4 (DPP-4) Inhibitors Step Therapy Program.....	7
Enhanced HMG-CoA Reductase Inhibitor (HMG) <i>Lipitor Non-Formulary</i> Step Therapy Program	16
Nasal Steroids Step Therapy Program.....	9
Proton Pump Inhibitors (PPI) [Generic] Step Therapy Program	13
Sedative Hypnotics.....	8
Selective Serotonin Reuptake Inhibitor (SSRI) Step Therapy Program.....	15
Serotonin and Norepinephrine Reuptake Inhibitors (SNRI) Step Therapy Program.....	12
Sodium Glucose Co-Transporter-2 (SGLT-2) Inhibitors Step Therapy Program.....	17
Tetracyclines (oral) Step Therapy Program.....	10

STEP THERAPIES*

Angiotensin Receptor Blocker (ARB) Step Therapy Program

- Atacand® (candesartan tablets – AstraZeneca, generic)
- Avapro® (irbesartan tablets – sanofi-aventis, generic)
- Benicar® (olmesartan tablets – Daiichi Sankyo)
- Cozaar® (losartan tablets – Merck, generic)
- Diovan® (valsartan tablets – Novartis, generic)
- Edarbi® (azilsartan tablets – Takeda)
- Micardis® (telmisartan tablets – Boehringer-Ingelheim, generic)
- Teveten® (eprosartan tablets – AbbVie, generic)
- Atacand HCT® (candesartan/hydrochlorothiazide tablets – AstraZeneca, generic)
- Avalide® (irbesartan/hydrochlorothiazide tablets – sanofi-aventis, generic)
- Benicar HCT® (olmesartan/hydrochlorothiazide tablets – Daiichi Sankyo)
- Diovan HCT® (valsartan/hydrochlorothiazide tablets – Novartis, generic)
- Edarbyclor® (azilsartan/chlorthalidone tablets – Takeda)
- Hyzaar® (losartan/hydrochlorothiazide tablets – Merck, generic)
- Micardis® HCT (telmisartan/hydrochlorothiazide tablets – Boehringer Ingelheim, generic)
- Teveten® HCT (eprosartan/hydrochlorothiazide tablets – AbbVie)
- Azor® (olmesartan/amlodipine tablets – Daiichi Sankyo Pharma)
- Exforge® (valsartan/amlodipine tablets – Novartis, generic)
- Exforge HCT® (valsartan/amlodipine/hydrochlorothiazide tablets – Novartis, generic)
- Tribenzor® (olmesartan/amlodipine/hydrochlorothiazide tablets – Daiichi Sankyo)

- Twynsta® (telmisartan/amlodipine tablets – Boehringer Ingelheim, generic)

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

Step 2: Atacand HCT, Atacand, Avalide, Avapro, Azor, Benicar, Benicar HCT, Cozaar, Diovan, Diovan HCT, Edarbi, Edarbyclor, Exforge, Exforge HCT, Hyzaar, Micardis, Micardis HCT, Teveten, Teveten HCT, Twynsta Tribenzor and Prexxartan.

CRITERIA

1. Authorization for a Step 2 product can be made if a patient has tried one Step 1 product.
2. Authorization may be given for a Step 2 product if the patient was recently hospitalized and discharged within the previous 30 days for a CV event (e.g., MI, hypertensive emergency, decompensated HF) and has already been started and stabilized on the agent.
3. Authorization may be given for Prexxartan if the patient has difficulty swallowing tablets.

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

- diclofenac epolamine topical patch (Flector[®] Patch – Pfizer)
- diclofenac potassium capsules (Zipsor[™] – Depomed)
- diclofenac potassium for oral solution (Cambia[™] – Depomed)
- diclofenac sodium extended-release tablets (Voltaren XR[®] – Novartis, generics)
- diclofenac capsules (Zorvolex[™] – Iroko Pharmaceuticals)
- diclofenac sodium topical gel (Voltaren[®] Gel 1% – Novartis, generic)
- diclofenac sodium topical solution (Pennsaid[®] 1.5% [generic] and 2% – Mallinckrodt, Klofensaid II 1.5% – PurTek Corporation/IGI Laboratories, generics)
- diclofenac sodium and misoprostol tablets (Arthrotec[®] – Pfizer, generics)
- etodolac capsules and tablets (Lodine[®] – Wyeth Pharmaceuticals, generics)
- fenoprofen capsules and tablets (Nalfon[®] – Pedinol Pharmacal Inc., generics)
- fenoprofen capsules (fenoprofen capsules [brand], Fenortho – KLE2, Inc/BPI)
- flurbiprofen tablets (Ansaid[®] – Pharmacia and Upjohn, generics)
- ibuprofen tablets and oral suspension (Motrin[®]/Advil[®] [OTC] – Pharmacia and Upjohn, generics)
- ibuprofen and famotidine tablets (Duexis[®] – Horizon Pharma)
- indomethacin capsules and oral suspension (Indocin[®] – Merck, generics)
- indomethacin capsules (Tivorbex[™] – Iroko Pharmaceuticals)
- ketorolac nasal spray (Sprix[®] – Egalet US, Inc.)
- mefenamic acid capsules (Ponstel[®] – First Horizon Pharmaceutical Corporation, generics)
- meloxicam tablets and oral suspension (Mobic[®] – Boehringer Ingelheim, generics)
- meloxicam capsules (Vivlodex[™] – Iroko Pharmaceuticals)
- naproxen oral suspension and tablets (Naprosyn[®] – Hoffmann-LaRoche, generics)
- naproxen enteric-coated tablets (EC-Naprosyn[®] – Roche, generics)
- naproxen controlled-release tablets (Naprelan[®] – Alkermes [a subsidiary of Alvogen Pharma], generics)
- naproxen sodium tablets and extended-release tablets (Anaprox[®], Anaprox DS[®] Aleve [OTC] – Hoffmann-LaRoche, generics)
- naproxen and esomeprazole magnesium delayed-release tablets (Vimovo[™] – Horizon Pharma)
- oxaprozin tablets (Daypro[®] – GD Searle LLC, generics)
- piroxicam capsules (Feldene[®] – Pfizer Laboratories, generics)

Generic NSAIDs**Step 1a NSAIDs (generic):**

diclofenac sodium (IR and ER)	ibuprofen	nabumetone
diclofenac potassium	indomethacin (IR and ER)	naproxen
diclofenac sodium and misoprostol	ketoprofen (IR and ER)	naproxen sodium (IR and ER)
diclofenac sodium topical solution 1.5% *	ketorolac [tablets]	oxaprozin
etodolac (IR and ER)	meclofenamate	piroxicam
fenoprofen	mefenamic acid	sulindac
flurbiprofen	meloxicam	tolmetin sodium

Step 2a NSAID (brand):

Anaprox, Anaprox DS	Feldene	Ponstel
Ansaid	Indocin	Sprix
Arthrotec	Klofensaid II*	Tivorbex
Cambia	Mobic	Vivlodex
Cataflam	Motrin	Voltaren XR
Daypro	Nalfon	Voltaren Gel 1% *
Diclofenac sodium 1% topical gel*	Naprelan and generics	Zipsor
Fenoprofen 400 mg (brand)	Naprosyn, EC-Naprosyn,	Zorvolex
	naproxen suspension	

Flector Patch*

Pennsaid 1.5% and 2%*

Fenortho
Lodine
Qmiiz
Licart

* Denotes topical product

Vimovo

Step 1b (brand or generic):

Prescription naproxen sodium

Prescription naproxen

AND

Prescription dextansoprazole

Prescription omeprazole magnesium

Prescription esomeprazole magnesium

Prescription omeprazole/sodium bicarbonate

Prescription esomeprazole strontium

Prescription pantoprazole (oral)

Prescription lansoprazole

Prescription rabeprazole

Prescription omeprazole

Step 2b NSAID:

Vimovo

Duexis

Step 1c (brand or generic):

Prescription ibuprofen (oral)

AND

Prescription cimetidine (oral)

Prescription nizatidine (oral)

Prescription famotidine (oral)

Prescription ranitidine (oral)

Step 2c NSAID:

Duexis

Criteria

Generic NSAIDs

1. If a patient has tried two unique generic prescription-strength NSAIDs for the current condition, then authorization for a brand name NSAID may be given. Note: Over-the-counter (OTC) NSAIDs count as alternatives when the patient used prescription-strength doses.
2. For patients who have difficulty swallowing or cannot swallow, authorization may be given for Sprix, Pennsaid 2%, Flector Patch, Klofenaid II, diclofenac sodium 1% topical gel, or Voltaren Gel if the patient has tried generic diclofenac sodium topical solution 1.5%.
3. For patients with a chronic musculoskeletal pain condition (e.g., OA) who will be applying Pennsaid 2%, Klofenaid II, diclofenac sodium 1% topical gel, or Voltaren Gel to ≤ 3 joints/sites (i.e., hand, wrist, elbow, knee, ankle, or foot each count as one joint site) who are at risk of NSAID-associated toxicity (e.g., patients with a previous GI bleed, history of peptic ulcer disease, impaired renal function, CV disease, hypertension, heart failure, elderly patients with impaired hepatic function or taking concomitant anticoagulants) authorization for Pennsaid 2%, Klofenaid II, diclofenac sodium 1% topical gel, or Voltaren Gel may be given if the patient has tried generic diclofenac sodium topical solution 1.5%. Significantly lower blood levels are achieved with the topical NSAIDs compared to the oral NSAIDs.²⁷⁻²⁸

4. For patients ≥ 75 years of age with hand or knee OA, authorization may be given for Pennsaid 2%, Klotensaid II, diclofenac sodium 1% topical gel, or Voltaren Gel if the patient has tried generic diclofenac sodium topical solution 1.5%. The 2012 ACR OA guidelines state that in patients ≥ 75 years of age, topical NSAIDs are preferred over oral NSAIDs for hand and knee OA.³³

Vimovo

1. Coverage of Vimovo is recommended if the patient has tried both one prescription proton pump inhibitor (PPI) [e.g., omeprazole, lansoprazole, pantoprazole] and one prescription naproxen product (brand or generic). Coverage of Vimovo is not recommended if the patient has only tried OTC naproxen, other NSAIDs besides naproxen, a COX-2 inhibitor (Celebrex), or OTC PPIs.

Duexis

1. Coverage of Duexis is recommended if the patient has tried both one prescription histamine₂ receptor antagonist (H₂RA) [e.g., famotidine, ranitidine, nizatidine] and one prescription ibuprofen product (brand or generic). Coverage of Duexis is not recommended if the patient has only tried OTC ibuprofen, other NSAIDs besides ibuprofen, a COX-2 inhibitor (Celebrex), or OTC H₂RAs.

Cyclooxygenase-2 (COX-2) Inhibitor Step Therapy Program

- Celebrex

Step 1 (oral NSAIDs):

diclofenac sodium (IR and ER)	ibuprofen	
diclofenac potassium	indomethacin (IR and ER)	
etodolac (IR and ER)		oxaprozin
	ketorolac (oral)	piroxicam
flurbiprofen	meclofenamate	sulindac
nabumetone		mefenamic acid
meloxicam	diclofenac sodium and misoprostol	

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

Step 2: generic celecoxib

Step 3: Brand Celebrex

CRITERIA

5. Approve the Step 2 product (generic celecoxib) for 1 year if the patient meets one of the following (A, B, C, D, E, F, G, or H):
 - A) The 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) The patient is currently taking chronic systemic corticosteroid therapy (e.g., prednisone), warfarin, clopidogrel, Effient® (prasugrel tablets), Brilinta™ (ticagrelor tablets), Xarelto® (rivaroxaban tablets), 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) The patient has reduced platelet counts or other coagulation disorders; OR
 - D) The patient has familial adenomatous polyposis (FAP) and is using the product to reduce the number of adenomatous colorectal polyps; OR
 - E) The patient is > 75 years of age and is using celecoxib for a chronic condition; OR
 - F) The patient has had a documented upper gastrointestinal bleed from a duodenal or gastric ulcer; OR
 - G) The patient has a past hypersensitivity, anaphylactic or allergic-type reaction (e.g., erythema, hives, urticaria, angioedema) to aspirin or NSAIDs; OR
 - H) The patient has aspirin-sensitive asthma (also known as aspirin-induced asthma, aspirin-exacerbated respiratory disease) or NSAID-induced asthma.
6. Approve the Step 2 product (generic celecoxib) for 30 days if the patient is using the agent during the preoperative/perioperative/postoperative period.
7. Approve the Step 3 product (brand Celebrex) for 1 year if the patient meets the following (A and B):
 - A) The 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; ANDThe 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/Eli Lilly)
- Jentadueto® XR (linagliptin/metformin extended-release tablets – Boehringer Ingelheim/Eli Lilly)
- Kazano™ (alogliptin/metformin tablets – Takeda)
- Kombiglyze™ XR (saxagliptin/metformin extended-release tablets – Bristol-Meyers Squibb)
- Nesina® (alogliptin tablets – Takeda)
- Onglyza® (saxagliptin tablets – Bristol-Meyers Squibb)
- Oseni™ (alogliptin/pioglitazone tablets – Takeda)
- Tradjenta® (linagliptin tablets – Boehringer Ingelheim/Eli Lilly)

Step 1: : metformin, metformin extended-release, Glucophage, Glucophage XR, Glumetza, Fortamet, Riomet, Avandamet, Actoplus Met, pioglitazone/metformin, Actoplus Met XR, Glucovance, metformin/glyburide, Prandimet, repaglinide/metformin, metformin/glipizide, Invokamet, Synjardy (empagliflozin/metformin tablets), Xigduo XR, Segluromet.

Step 2: Januvia, Janumet, Janumet XR, Onglyza, Kombiglyze XR, Tradjenta, Jentadueto, Jentadueto XR, Nesina, alogliptin, Kazano, alogliptin/metformin, Oseni, alogliptin/pioglitazone

CRITERIA

Exceptions can be made in patients meeting one of the following criteria:

1. If the patient has tried metformin or a metformin-containing combination product (brand or generic) in the past, then authorization for a Step 2 product (excluding Juvisync) may be given.
2. If the patient is already started on a DPP-4 inhibitor approve a Step 2 product (excluding Juvisync).
3. If the patient has tried a DPP-4 inhibitor (or DPP-4 inhibitor containing product [not including Juvisync]), then authorization for Juvisync may be given.
4. If the patient has tried Juvisync, then authorization for a Step 2 product (excluding Juvisync) may be given.
5. If the patient is initiating dual (combination) therapy with Januvia, Onglyza, Tradjenta, Nesina or alogliptin AND metformin, then authorization may be given for Januvia, Onglyza, Tradjenta, Nesina, or alogliptin without a trial of metformin.
6. If the patient has a contraindication to metformin, according to the prescribing physician, then authorization for Januvia, Onglyza, Tradjenta, Nesina, or alogliptin may be given without a trial of metformin.
7. No other exceptions for Step 2 agents are recommended.

Sedative Hypnotics

- Ambien[®] (zolpidem tablets - Sanofi-Aventis, generics)
- Ambien CR[™] (zolpidem extended-release tablets – Sanofi-Aventis, generics)
- Belsomra[®] (suvorexant tablets – Merck)
- Edluar[™] (zolpidem 5 and 10 mg sublingual tablets – Meda Pharmaceuticals)
- Intermezzo[®] (zolpidem 1.75 and 3.5 mg sublingual tablets – Transcept Pharmaceuticals/Purdue Pharma)
- Lunesta[™] (eszopiclone tablets – Sepracor)
- Rozerem[™] (ramelteon tablets – Takeda)
- Silenor[®] (doxepin 3 and 6 mg tablets – Somaxon Pharmaceuticals)
- Sonata[®] (zaleplon capsules – King Pharmaceuticals, generics)
- Zolpimist[™] (zolpidem oral spray – NovaDel Pharma)

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, Edluar, Intermezzo, Lunesta, Rozerem, Silenor, generic doxepin 3 mg and 6 mg tablets, Sonata, Zolpimist

CRITERIA

1. If the patient has tried a Step 1 agent, then approve a Step 2 agent.
2. Exceptions can be made for Silenor or generic doxepin 3 mg and 6 mg tablets if the patient has a documented history of addiction to controlled substances.
3. An exception for Silenor or generic doxepin 3 mg and 6 mg tablets can be made in patients ≥ 65 years of age.
4. Exceptions can be made for Edluar or Zolpimist if the patient has difficulty swallowing or cannot swallow tablets.
5. No other exceptions are recommended.

Nasal Steroids Step Therapy Program

- Beconase AQ[®] (beclomethasone nasal spray – GlaxoSmithKline)
- Dymista[®] (azelastine hydrochloride/fluticasone propionate nasal spray – MEDA)
- Flonase[®] (fluticasone propionate nasal spray – GlaxoSmithKline, generics [brand and generic no longer marketed])
- flunisolide nasal spray – generics
- Nasacort[®] Allergy 24HR/Child Nasacort[®] Allergy 24HR over-the-counter (OTC) [triamcinolone nasal spray – Chattem, generics]
- Nasacort AQ[®] (triamcinolone nasal spray – Sanofi-Aventis, generics [brand no longer marketed])
- Nasonex[®] (mometasone nasal spray – Schering-Plough)
- Omnaris[®] (ciclesonide nasal spray – Sepracor)
- Qnasl[®] (beclomethasone dipropionate nasal aerosol – Teva)
- Rhinocort[®] Allergy Spray OTC (budesonide nasal spray – Johnson & Johnson/McNeil Consumer Healthcare, generics)
- Rhinocort Aqua[®] (budesonide nasal spray – AstraZeneca, generics)
- Veramyst[®] (fluticasone furoate nasal spray – GlaxoSmithKline)
- Zetonna[®] (ciclesonide nasal aerosol – Sunovion)

Step 1: fluticasone propionate nasal spray

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

CRITERIA

1. If the patient has tried a Step 1 product, then authorization for a Step 2 product may be given.
2. Authorization for mometasone furoate nasal spray, Nasonex, or Veramyst may be given for patients < 4 years of age.
3. Exceptions for other conditions or situations are not recommended.

Tetracyclines (oral) Step Therapy Program

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

- Acticlate™ (doxycycline hyclate tablets – Aqua Pharmaceuticals)
- Adoxa® (doxycycline monohydrate tablets – Sandoz, generics)
- Alodox™ Convenience Kit (doxycycline hyclate tablets – OCuSOFT)
- Avidoxy™ DK Kit (doxycycline monohydrate tablets – Avidas Pharmaceuticals)
- Doryx® (doxycycline hyclate delayed-release tablets - Mayne Pharma; generics for some strengths)
 - Doryx® MPC (doxycycline hyclate delayed-release tablets – Mayne Pharma)
-
- Doxycycline IR-DR 40 mg capsules (Owen Laboratories [brand product])
- Minocin® (minocycline hydrochloride pellet-filled capsules – Valeant, generics)
- Minocin® Kit (minocycline hydrochloride pellet-filled capsules – Valeant)
- Monodox® (doxycycline monohydrate capsules – Aqua, generics)
 - Monodoxyne™ NL (doxycycline monohydrate capsules – IntraDerm)
-
- Morgidox® Kit (doxycycline hyclate capsules – Medimetriks)
- Oracea™ (doxycycline delayed-release capsules – Galderma)
- Solodyn® (minocycline hydrochloride extended-release tablets – Valeant or Medicis, generics for some strengths)
- Vibramycin® (doxycycline hyclate capsules – Pfizer, generics)
- Targadox™ (doxycycline hyclate tablets – Journey Medical Corporation)

Step 1: Generic solid dosage forms (e.g., capsules, tablets): demeclocycline, doxycycline, minocycline, tetracycline, Avidoxy, Morgidox, Monodoxy NL

Step 2: Acticlate, Avidoxy DK Kit, Doryx, Doryx MPC, Doxycycline IR-DR* 40 mg capsules (brand product), Minocin, Minolira Monodox, Morgidox Kit, Oracea, Seysara, Solodyn (brand and generics), Targadox, Vibramycin, Ximino

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

CRITERIA

1. If the patient has tried a Step 1 product, approve a Step 2 product.
2. No other exceptions are recommended.

Antidepressant Step Therapy Program – Bupropion

- Aplenzin® (bupropion hydrobromide extended-release tablets – Valeant)
- Forfivo XL (bupropion hydrochloride extended-release tablets – Edgemont)
- Wellbutrin SR® (bupropion hydrochloride sustained-release tablets – GlaxoSmithKline, generics)
- Wellbutrin XL® (bupropion hydrochloride extended-release tablets – Valeant, generics)

Step 1: generic bupropion sustained-release tablets, generic bupropion extended-release tablets

Step 2: Aplenzin, Forfivo XL, Wellbutrin SR, Wellbutrin XL

RECOMMENDED CRITERIA

1. If a patient has tried a generic bupropion sustained- or extended-release tablet, then authorization for a Step 2 product may be given. If the patient has tried bupropion immediate-release tablets, they must try a generic sustained- or extended-release tablet before receiving authorization for a Step 2 product.
2. No other exceptions are recommended.

Serotonin and Norepinephrine Reuptake Inhibitors (SNRI) Step Therapy Program

- Cymbalta[®] (duloxetine HCl delayed-release capsules – Lilly, generics)
- Desvenlafaxine extended-release tablets (Alembic /Ranbaxy [brand product])
- Desvenlafaxine fumarate extended-release tablets (Sun Pharma/Caraco [brand product])
- Effexor[®] (venlafaxine HCl tablets – Wyeth, generics)
- Effexor[®] XR (venlafaxine HCl extended-release capsules – Wyeth, generics)
- Fetzima[®] (levomilnacipran HCl extended-release capsules – Forest)
- Irenka[™] (duloxetine 40 mg delayed-release capsules – Lupin, generic)
- Khedezla[™] (desvenlafaxine extended-release tablets – Osmotica/Macoven)
- Pristiq[®] (desvenlafaxine succinate extended-release tablets – Wyeth)
- Savella[®] (milnacipran HCl tablets – Forest)
- Venlafaxine HCl extended-release tablets (Upstate Pharma/Osmotica [brand product], generics)

Step 1: citalopram tablets (Celexa, generic), generic citalopram oral solution, fluoxetine immediate-release capsules and tablets (Prozac, Sarafem, generic), generic fluoxetine oral solution, fluoxetine delayed-release capsules (Prozac Weekly, generics), generic fluvoxamine immediate-release tablets, generic fluvoxamine extended-release capsules (Luvox CR, generics), paroxetine HCl immediate- and controlled-release tablets (Paxil, Paxil CR, generic), paroxetine oral suspension (Paxil, generic), sertraline tablets (Zoloft, generic), sertraline oral solution (Zoloft, generic), escitalopram tablets (Lexapro, generic), escitalopram oral solution (Lexapro, generic), Pexeva, Trintellix (formerly Brintellix), Viibryd, generic duloxetine delayed-release capsules, generic generic desvenlafaxine succinate extended-release tablets, generic venlafaxine immediate-release tablets, venlafaxine immediate-release tablets, generic venlafaxine extended-release capsules, generic venlafaxine extended-release tablets

Step 2: Effexor, Effexor XR, Cymbalta, Pristiq, Desvenlafaxine extended-release tablets (brand product), Desvenlafaxine fumarate extended-release tablets (brand product), Venlafaxine extended-release tablets (brand product), Savella, Khedezla, Fetzima, Irenka

Criteria

1. If a patient has tried one Step 1 product, then authorization for a Step 2 product (other than Savella) may be given.
2. If a patient has tried at least two other agents (e.g., SSRI, SNRI, TCA, bupropion), then authorization for Savella may be given.
3. Exceptions can be made for Savella if the patient is treating fibromyalgia (with or without depression).
4. Patients who are currently taking or who have taken brand name Desvenlafaxine extended-release tablets, Desvenlafaxine fumarate extended-release tablets, Khedezla, or Fetzima at any time in the past and discontinued their use may receive authorization for the SNRI that they have used.
5. Exceptions can be made for Desvenlafaxine extended-release tablets, Desvenlafaxine fumarate extended-release tablets, Khedezla, or Fetzima if the patient has suicidal ideation.

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

- Aciphex[®], Aciphex[®] Sprinkle[™] (rabeprazole delayed-release tablets and delayed-release capsules – Janssen Pharmaceutica, generics [tablets only])
- Dexilant[™] (dexlansoprazole delayed-release capsules – Takeda)
- Esomeprazole strontium delayed-release capsules – Amneal Pharmaceuticals
- Nexium[®] (esomeprazole delayed-release capsules, delayed release oral suspension [granules] – AstraZeneca, generics [capsules only])
- Prevacid[®], Prevacid[®] SoluTab[™] (lansoprazole delayed-release capsules, delayed-release orally disintegrating tablets – Takeda, generics [capsules only])
- Prevacid[®] 24HR (lansoprazole delayed-release capsules – Novartis, generics)
- Prilosec[®] (omeprazole delayed-release capsules, delayed release oral suspension [granules] – AstraZeneca, generics [capsules only])
- Prilosec OTC[®] (omeprazole magnesium delayed-release tablets – Procter & Gamble, generics)
- Protonix[®] (pantoprazole delayed-release tablets, delayed release oral suspension [granules] – Wyeth Ayerst, generics [tablets only])
- Zegerid[®] (omeprazole/sodium bicarbonate capsules, powder for oral suspension – Santarus, generics [capsules only])
- Zegerid OTC[®] (omeprazole/sodium bicarbonate capsules – Schering Plough)

Automation: Patients with a history of one Step 1 drug within the 130-day look-back period are excluded from step therapy. This policy contains automation for patients who have received Nexium 24HR (OTC) and select generic omeprazole/bicarbonate products. **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, generic lansoprazole orally disintegrating tablets

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

CRITERIA

1. If the patient has tried a Step 1 PPI under the supervision of a physician, then authorization may be given for a Step 2 PPI 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.
2. If the patient is < 1 year of age, then authorization may be given for 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). Both Nexium and Prilosec are indicated down to 1 month of age.^{7,11}

3. If the requested drug is Zegerid, Zegerid OTC, or generic omeprazole/sodium bicarbonate (Rx or OTC), authorization may be given 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.

Selective Serotonin Reuptake Inhibitor (SSRI) Step Therapy Program

- Brisdelle® (paroxetine 7.5 mg capsules – Noven Therapeutics)
- Celexa® (citalopram tablets and oral solution – Forest, generics)
- Fluoxetine 60 mg tablets (branded product) – Edgemont
- fluvoxamine tablets (generics)
- Lexapro® (escitalopram tablets and oral solution – Forest, generics)
- Luvox® CR (fluvoxamine extended-release capsules – Jazz, generics)
- Paxil® (paroxetine hydrochloride tablets and oral suspension – GlaxoSmithKline, generics)
- Paxil CR® (paroxetine hydrochloride controlled-release tablets – GlaxoSmithKline, generics)
- Pexeva® (paroxetine mesylate tablets – JDS Pharmaceuticals)
- Prozac® (fluoxetine capsules, tablets, and oral solution – Lilly, generics)
- Prozac® Weekly™ (fluoxetine delayed-release capsules – Lilly, generics)
- Sarafem® (fluoxetine capsules – generics only)
- Sarafem® (fluoxetine tablets – Warner Chilcott)
- Trintellix™ (formerly Brintellix®) [vortioxetine tablets – Takeda]
- Viibryd® (vilazodone hydrochloride tablets – Forest)
- Zoloft® (sertraline tablets and oral solution – Pfizer, generics)

Step 1 SSRIs: generic citalopram tablets, generic citalopram oral solution, generic escitalopram tablets, generic escitalopram oral solution, generic fluoxetine immediate-release capsules, generic fluoxetine oral solution, generic fluvoxamine immediate-release tablets, generic paroxetine HCl immediate-release tablets, generic paroxetine HCl oral suspension, generic sertraline tablets, generic sertraline oral solution, generic fluoxetine delayed-release 90 mg capsule

Step 2 SSRIs: Fluoxetine 60 mg tablets (branded product), Lexapro, Paxil, Paxil CR, Pexeva, Prozac Weekly, Sarafem, Celexa, Zoloft, Luvox CR, Viibryd, Trintellix (formerly Brintellix), Brisdelle, generic fluoxetine immediate-release tablets, generic paroxetine HCl controlled-release (CR)/extended-release (ER) tablets, generic paroxetine mesylate capsules, generic fluvoxamine extended-release capsules

Note: This policy has two different sets of criteria, one requires that one generic SSRI be used first (“standard criteria”) and the other requires that two generic SSRIs be used first (“high impact criteria”).

Standard Criteria

1. If a patient has tried *one* generic SSRI, then authorization for a Step 2 product may be given.
2. Patients who are currently taking or who have taken Pexeva, Viibryd, or Brintellix at any time in the past and discontinued their use may receive authorization for the SSRI that they have used.
3. Exceptions for Pexeva, Viibryd, and Brintellix can be made for patients with suicidal ideation.

High Impact Criteria

1. If a patient has tried *two* generic SSRIs, then authorization for a Step 2 product may be given.
2. Patients who are currently taking or who have taken Pexeva, Viibryd, or Brintellix at any time in the past and discontinued their use may receive authorization for the SSRI that they have used.
3. Exceptions for Pexeva, Viibryd, and Brintellix can be made for patients with suicidal ideation.

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

- Lipitor® (atorvastatin tablets – Pfizer, generic)
- Lescol® (fluvastatin capsules – Novartis, generic)
- Lescol® XL (fluvastatin extended-release tablets – Novartis, generic)
- Mevacor® (lovastatin tablets – Merck, generic)
- Altoprev® (lovastatin extended-release tablets – Andrx)
- Pravachol® (pravastatin tablets – Bristol-Myers Squibb, generic)
- Crestor® (rosuvastatin tablets – AstraZeneca, generic)
- Zocor® (simvastatin tablets – Merck, generic)
- Caduet® (atorvastatin/amlodipine tablets – Pfizer, generic)
- Vytorin® (ezetimibe/simvastatin tablets – Merck)
- Livalo® (pitavastatin tablets – Lilly/Kowa)

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

Step 2 HMGs: , Livalo, **Step 3 HMGs:** Flolipid, Lescol, Lescol XL, Mevacor, Altoprev, Pravachol, Zocor, Lipitor, Crestor, Vytorin and Caduet.

CRITERIA

1. Authorization may be given for a Step 2 HMG if the patient has tried one Step 1 HMG (as a brand or a generic).
2. Authorization may be given for a Step 3 HMG if the patient has tried one Step 1 HMG (as a brand or a generic) AND one Step 2 HMG.
3. Authorization may be given for Flolipid for patients who cannot or have difficulty swallowing tablets or capsules.

DIABETIC TEST STRIP PREFERRED STEP THERAPY POLICY

Automation: Patients with a history of two Step 1 drugs within the 120-day look-back period are excluded from step therapy.

Basic Formulary and National Preferred Formulary:

Step 1: Abbott (e.g., Freestyle, Freestyle Lite, Freestyle InsuLinx, Optium EZ, Optium, Precision PCX, Precision PCX Plus, Precision Point of Care, Precision Q-I-D, Precision Xtra, Ultima) [Note: Abbott Freestyle Precision Neo is in Step 2], Lifescan (e.g., OneTouch Ultra, OneTouch Verio).

Step 2: All others (e.g., Ascensia/Bayer [e.g., Breeze 2, Contour, Contour Next], Abbott Freestyle Precision Neo, Roche [e.g., Accu-Chek Aviva Plus, Accu-Chek Compact Plus, Accu-Chek Guide, Accu-Chek Smartview], Trividia/Nipro [e.g., TRUE FOCUS, TRUE METRIX, TRUEtrack]).

CRITERIA

1. If the patient has tried a Step 1 product, approve a Step 2 product.
2. For patients who use an insulin pump/meter system that is not compatible with a Step 1 test strip, then authorization for a Step 2 product may be given (e.g., Accu-Chek combo/ Accu-Chek Aviva Plus test strips,

MiniMed 530 G/ Contour Next, MiniMed Paradigm Real Time Revel/Contour Next, Guardian Real-Time continuous glucose monitor/Next test strips).

3. No other exceptions are recommended.

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

DRUGS AFFECTED:

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

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

This policy contains automation for patients who have received or are currently receiving an SGLT-2 inhibitor (e.g., Farxiga, Invokana, Jardiance, Steglatro), or an SGLT-2 inhibitor/metformin combination product (e.g., Invokamet, Invokamet XR, Segluromet, Synjardy, Synjardy XR, Xigduo XR).

Step 1: metformin, metformin-extended release, Fortamet ER, Glucophage, Glucophage XR, Glumetza ER, Riomet solution, Glucovance, glyburide-metformin, glipizide-metformin, ActoplusMet, pioglitazone-metformin, Actoplus Met XR, Avandamet, Prandimet, repaglinide/metformin, Kazano, alogliptin/metformin, Jentadueto, Jentadueto XR, Kombiglyze XR, Janumet, Janumet XR.

Step 2: Farxiga, Invokana, Invokamet, Invokamet XR, Jardiance, Xigduo XR, Synjardy, Synjardy XR, Segluromet, Steglatro.

Criteria

1. If the patient has tried one Step 1 product, authorization for a Step 2 product may be given.
2. If the patient will be initiating dual-therapy with metformin AND a single-entity Step 2 sodium glucose co-transporter-2 (SGLT-2) inhibitor, approve a single-entity Step 2 SGLT-2 inhibitor.
3. If the patient has been started on a Step 2 agent, approve the Step 2 product (patients are not required to go back and try a Step 1 product).
4. 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 metabolic acidosis, including diabetic ketoacidosis).

5. For patients with heart failure with reduced ejection fraction, authorization for Farxiga may be given.
6. No other exceptions are recommended.

Diabetes – Glucagon-Like Peptide-1 (GLP-1) Agonists Preferred Step Therapy

DRUGS AFFECTED:

- Adlyxin™ (lixisenatide injection – SanofiAventis)
- Bydureon® (exenatide extended-release for injectable suspension – AstraZeneca)
- Bydureon® BCise™ (exenatide extended release injectable suspension – AstraZeneca)
- Byetta® (exenatide injection – AstraZeneca)
- Tanzeum™ (albiglutide for subcutaneous injection – GlaxoSmithKline [discontinued])
- Trulicity™ (dulaglutide injection – Eli Lilly)
- Victoza® (liraglutide [rDNA origin] injection – NovoNordisk)
- Ozempic® (semaglutide injection – Novo Nordisk)

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

Step 1: Bydureon, Bydureon BCise, Byetta, Ozempic, Rybelsus, Trulicity

Step 2: Adlyxin, Tanzeum, Victoza

CRITERIA

5. If the patient has tried a Step 1 product, approve a Step 2 product.
2. If the patient has stage 3 chronic kidney disease (CKD) or severe renal impairment (creatinine clearance [CrCl] < 30 mL/min) according to the prescribing physician, approve the requested Step 2 product.
3. If, according to the prescribing physician, the patient meets ONE of the following (criteria a through g), approve Victoza.
 - a) The patient has a history of a myocardial infarction (MI); OR
 - b) The patient has a history of stroke or transient ischemic attack; OR
 - c) The patient has undergone at least one prior coronary, carotid, or peripheral arterial revascularization procedure; OR
 - d) The patient has significant stenosis of coronary, carotid, or lower extremity arteries; OR
 - e) The patient has a history of symptomatic coronary heart disease (CHD) or unstable angina; OR
 - f) The patient has chronic heart failure; OR
 - g) The patient has chronic renal failure (estimated creatinine clearance [CrCl] < 60 mL/min).
4. No other exceptions are recommended.

Diabetes – Dipeptidyl Peptidase-4 (DPP-4) Inhibitors Preferred Step Therapy**DRUGS AFFECTED:**

- * Janumet® (sitagliptin/metformin tablets – Merck)
- * Janumet® XR (sitagliptin/metformin extended-release tablets – Merck)
- * Januvia® (sitagliptin tablets – Merck)
- * Jentadueto® (linagliptin/metformin tablets – Boehringer Ingelheim/Eli Lilly)
- * Jentadueto® XR (linagliptin/metformin extended-release tablets – Boehringer Ingelheim/Eli Lilly)
- * Kazano™ (alogliptin/metformin tablets – Takeda, generics)
- * Kombiglyze™ XR (saxagliptin/metformin extended-release tablets – Bristol-Meyers Squibb)
- * Nesina® (alogliptin tablets – Takeda, generics)
- * Onglyza® (saxagliptin tablets – Bristol-Meyers Squibb)
- * Tradjenta® (linagliptin tablets – Boehringer Ingelheim/Eli Lilly)

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

Step 1: Januvia, Janumet, Janumet XR, Tradjenta, Jentadueto, Jentadueto XR.

Step 2: Nesina, alogliptin, Kazano, alogliptin/metformin, Onglyza, Kombiglyze XR

CRITERIA

4. If the patient has tried a Step 1 product, approve a Step 2 product.

5. No other exceptions are recommended.

Diabetes – Insulin (Other) Preferred Step Therapy

DRUGS AFFECTED:

- Humulin® R (Regular insulin human injection, USP [rDNA origin] U-100 only [vials] - Lilly)
- Humulin® N (NPH, human insulin isophane suspension [recombinant DNA origin] injection [vials and KwikPen] – Lilly)
- Humulin® 70/30 (70% NPH, human insulin isophane suspension and 30% regular, human insulin injection [recombinant DNA origin] [vials, and KwikPen] – Lilly)
- Novolin® N (NPH, human insulin isophane suspension [recombinant DNA origin] injection [vials] - NovoNordisk)
- Novolin® R (Regular, human insulin injection [recombinant DNA origin] solution for subcutaneous or intravenous use [vials] – NovoNordisk)
- Novolin® 70/30 (70% NPH, human insulin isophane suspension and 30% regular, human insulin [recombinant DNA origin] injection [vials] – NovoNordisk)

Regular Insulins

Step 1: Humulin R vials

Step 2: Novolin R vials, ReliOn Novolin R vials

NPH Insulins

Step 1: Humulin N vials, Humulin KwikPens

Step 2: Novolin N vials, ReliOn Novolin N vials

70/30 Mix Insulins

Step 1: Humulin 70/30 vials, Humulin 70/30 KwikPens

Step 2: Novolin 70/30 vials, Novolin 70/30 FlexPens, ReliOn Novolin 70/30 vials, ReliOn Novolin 70/30 FlexPens

CRITERIA.

1. If a patient has tried Humulin R, approve Novolin R.
2. If a patient has tried Humulin N (vials KwikPens), approve Novolin N.
3. If a patient has tried Humulin 70/30 (vials KwikPens), approve Novolin 70/30.
4. No other exceptions are recommended.

Diabetes – Insulin (Rapid-Acting) Preferred Step Therapy

DRUGS AFFECTED:

- * Admelog® (insulin lispro injection – sanofi aventis)
- * Apidra® (insulin glulisine [rDNA origin] injection – sanofi aventis)
- * Fiasp® (insulin aspart injection – Novo Nordisk)
- * Humalog® (insulin lispro [rDNA origin] injection – Eli Lilly [U-100 and U-200])
- * Humalog® 50/50 mix (50% insulin lispro protamine suspension/ 50% insulin lispro [rDNA origin] injection – Eli Lilly)
- * Humalog® Mix 75/25 (75% insulin lispro protamine suspension/ 25% insulin lispro [rDNA origin] injection – Eli Lilly)
- * NovoLog® (insulin aspart [rDNA origin] injection – Novo Nordisk)
- * NovoLog Mix 70/30 (70% insulin aspart protamine suspension/ 30% insulin aspart [rDNA origin] injection – Novo Nordisk)

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

Step 1: Humalog vials, Humalog cartridges, Humalog prefilled insulin device (KwikPen), Humalog 50/50 mix vials, Humalog 50/50 mix prefilled insulin device (KwikPen), Humalog 75/25 mix vials, Humalog 75/25 mix prefilled insulin device (KwikPen).

Step 2: Admelog vials, Admelog SoloStar prefilled pen, Apidra vials, Apidra SoloStar prefilled pen, Fiasp vials, Fiasp FlexTouch, Fiasp PenFill cartridges, insulin aspart PenFill cartridges, insulin aspart FlexPen, insulin aspart vials, insulin aspart protamine FlexPen, insulin aspart protamine vials, insulin lispro prefilled insulin device (KwikPen U-100), insulin lispro vials (U-100), NovoLog vials, NovoLog PenFill cartridges, NovoLog FlexPen, Novolog 70/30 mix vials, Novolog 70/30 mix FlexPen.

CRITERIA.

1. If a patient has tried a Step 1 product approve a Step 2 product.
2. No other exceptions are recommended.

Author: Cynthia Wilhelmy, MD; Created: 12/5/06

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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) Step Therapy Program
7/24/18	No	Catherine Sanders, MD; Robert Sterling, MD	
10/23/18	Yes	Robert Sterling, MD	Adopted the Diabetes Step Therapy Policies: <ul style="list-style-type: none">• Diabetes – Dipeptidyl Peptidase-4 (DPP-4) Inhibitors Preferred Step Therapy• Diabetes- Glucagon-Like Peptide-1 (GLP-1) Agonist Preferred Step Therapy• Diabetes-Insulin (Other) Preferred Step Therapy• Diabetes-Insulin (Rapid Acting) Preferred Step Therapy
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: <ul style="list-style-type: none">• NSAIDS• Diabetes- Glucagon-Like Peptide-1 (GLP-1) Agonist Preferred Step 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 generic budesonide removed from Step 1 (products obsolete). Moved flunisolide nasal spray and mometasone furoate nasal spray from Step 1 to 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	<p>Effective 1/1/2020: Abbott test strips, except Freestyle Precision Neo, are Step 1 for both Basic and National Preferred Formularies. Freestyle Precision Neo test strips are Step 2 for both Basic and National Preferred Formularies.</p> <p>Rybelsus added to Step 1 (Basic/National Preferred Formularies) and to Step 2 (High Performance Formulary).</p> <p>Effective 1/1/2020: ReliOn Novolin R, ReliOn Novolin N, and ReliOn Novolin 70/30 products added to policy (Step 2)</p> <p>Authorized generics to NovoLog (insulin aspart FlexPen, PenFill cartridge, and vial) and NovoLog 70/30 mix (insulin aspart protamine FlexPen, vial) added to Step 2.</p>
04/28/20	Yes	Howard Taekman, MD; Robert Sterling, MD	<p>Generic ramelteon tablets were moved from Step 2 to Step 1. Additionally, generic doxepin 3 mg and 6 mg tablets were added to Step 2.</p> <p>Added generics to Dymista to Step 2. Removed Veramyst from Step 2 (product obsolete).</p> <p>Removed Ocudox Convenience Kit from Step 1 – obsolete</p> <p>Generic esomeprazole delayed release granules for oral suspension was added to Step 2 in the policy. The addition of generic esomeprazole delayed release granules for oral suspension (packets) for criteria of patient is < 1 year of age was put in as an option.</p> <p>4/7/2020: Addition of “capsules” to generic paroxetine mesylate listed in Step 2 medications.</p>

6/18/20	Yes	Howard Taekman, MD Robert Sterling, MD	<p>Update to the SGLT-2 Step Therapy Program: Added the following:</p> <p>If the patient has a contraindication to metformin, according to the prescriber, then authorization for Farxiga, Invokana, Jardiance, or Steglatro may be given. (<u>Note</u>: Examples of contraindications to metformin include acute or chronic metabolic acidosis, including diabetic ketoacidosis).</p> <p>For patients with heart failure with reduced ejection fraction, authorization for Farxiga may be given.</p>
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