STEP THERAPY IN MEDICARE PART D

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Objectives

- Why is this important?
- Medicare Part D
- Step Therapy Definition, Principles, and Process
- Common Step Therapy Programs
- Examples of Step Therapy Criteria
 - Health Net
 - Express Scripts (Value & Choice Plan)
 - Group Health Medicare Advantage HMO & PPO
 - BlueCross BlueShield of North Carolina
 - Medi-Cal
- Step Therapy Drug Request Form
- Application to Pharmacy
- Summary





Why is this Important?

- Awareness of the many barriers to control healthcare costs
- There are drugs that work just as well as other, more expensive, drugs.
- Not every drug is available to us.
- Awareness of the process of Step Therapy; it may affect our treatment options
- We need to work closely with our healthcare providers and follow up on the process to make sure we get the medications we need.

Medicare Part D – A Quick Overview

- Enacted as part of the Medicare Modernization Act of 2003
- US federal government program to subsidize costs of prescription drugs and prescription drug insurance premiums for Medicare beneficiaries
- Individuals are eligible for prescription drug coverage under a Part D plan if they are signed up for benefits under Medicare Part A and/or Part B
- Step therapy as it pertains to Medicare Part D is outlined and created by P&T Committees assigned by CMS



Step Therapy – Definition

- Definition per the Centers for Medicare and Medicaid (CMS):
 - "In some cases, plans require you to first try one drug before they will cover another drug for that condition. For example, if Drug A and Drug B both treat your medical condition, a plan may require your doctor to prescribe Drug A first. If Drug A does not work for you, then the plan will cover Drug B." (source: Medicare.gov)
- A type of prior authorization
- Enhanced drug utilization management process or a set of drug use protocols that promote the safe and costeffective use of a drug based on nationally accepted standards of care and well-documented clinical drug studies

Step Therapy – Principles

- The goal of step therapy is to reduce cost while providing appropriate clinical care
 - The patient must first try less expensive drugs that have proven effective for the particular condition before he/she may move up a "step" to a more expensive drug
 - Eg: generic drug → less expensive brand name drug → more expensive brand name drug
- Two Main Concepts need both
 - Clinical Approach: based on appropriate clinical guidelines
 - Related to formulary
 - Financial Approach: want to use the cheaper drug before the more expensive one



Step Therapy – the Process

- First-line drug is used **before** a claim can be processed for a second-line drug.
- If one or more Step 1 drugs exist in claims history, and/or valid clinical exceptions are documented, Step 2 drug claim will process automatically.

- Information needs to be provided to determine if Step 2 drug meets established use criteria (i.e. medical diagnosis)
- May need prior authorization (to be completed by physician)
- Treatment Authorization Request
- Look Back Period

Step

Step 2:

Step Therapy – Issues?

No-Medication Outcome

- A portion of members with a claim rejection at the pointof-service do not receive a medication in that class
- Two methods used by PBMs to decrease rate of nomedication outcome
 - Retrospective Drug Utilization Review (RetroDUR)
 - Providers notified of patients with step therapy rejection and have not yet obtained medication
 - Medical & Pharmacy Claims Integrated Smart Edit
 - Real-time integration of member's medical diagnosis at POS transaction
 - Patients with high-risk diagnoses may bypass the edit



Step Therapy – Common Programs

Core Area	First Line	Second Line	PMPM Savings	No Medication After Step- Therapy Claim Rejection
ADHD	Generic stimulants	Strattera or brand stimulants	No published data	No published data
Allergy	Nasal steroids	Leukotriene modifiers	No published data	No published data
Cholesterol	Generic statins	Brand statins	No published data	No published data
Depression ^{4,5}	Generic SSRIs	Brand SSRIs, brand SNRIs	\$0.00-\$0.36	11%
Gastrointestinals⁴	Generic PPI	Brand PPIs	\$0.48	22%
Hypertension ^{2,3}	Generic ACEIs	Brand ACEIs, brand ARBs	\$0.03-\$0.11	7%-9%
Pain⁴	Generic NSAIDs	Brand NSAIDs, COX-2s	\$0.29	15%
Pain	Generic gabapentin or tricyclic antidepressants	Lyrica or Topamax	No published data	No published data
Rheumatoid arthritis	Methotrexate	TNF-blockers	No published data	No published data

ACEIs = angiotensin-converting enzyme inhibitors; ARBs = angiotensin II receptor blockers; COX-2s = cyclooxygenase-2 inhibitors; NSAIDs = nonsteroidal anti-inflammatory drugs; PMPM = per member per month; PPIs = proton pump inhibitors; SNRIs = serotonin norepinephrine reuptake inhibitors; SSRIs = selective serotonin reuptake inhibitors; TNF = tumor necrosis factor.



Examples of Step Therapy Criteria

Type of Health Plan	ADHD	Allergy	Cholesterol	Depression	GI	Hypertension	Pain	RA
Health Net (Medicare-Medicaid Plan, HMO, PPO)			Х	Х	Х			
Express Scripts (Value & Choice Plan)	Х	Х	Х	Х	Х	Х	Х	Х
BlueCross BlueShield of North Carolina (Blue Medicare HMO Standard, Blue Medicare HMO Enhanced and Blue Medicare PPO)				Х			Х	Х
Medi-Cal							Х	Х
Group Health Medicare Advantage HMO & PPO	- Antisp	abetic Agen asmodics, a Medicatio	-	anuvia, Sulfonyl	ureas)			



Step Therapy – Health Net (Medicare-Medicaid Plan, HMO, PPO)

Drug Name	Step Therapy Criteria
APLENZIN (buproprion hbr)	Applies to all formularies except the Cal
	MediConnect Drug List
	Must have a paid claims history of one of the
	following:
	 mirtazapine, nefazodone, citalopram,
	escitalopram, fluoxetine, fluvoxamine,
	paroxetine, sertraline, duloxetine, venlafaxine,
	OR bupropion
BRINTELLIX (vortioxetine)	Must have a paid claims history of one of the
	following:
	 mirtazapine, nefazodone, citalopram,
	escitalopram, fluoxetine, fluvoxamine,
	paroxetine, sertraline, duloxetine, venlafaxine,
	OR bupropion
BYETTA (exenatide)	Must have a paid claims history of:
	 metformin HCL
BYDUREON (exenatide	Applies to all formularies except the Cal
extended release)	MediConnect Drug List
	Must have a paid claims history of:
	metformin HCL
CRESTOR (rosuvastatin	Applies to all formularies except the Cal
calcium)	MediConnect Drug List
	Must have a paid claims history of:
	 atorvastatin calcium
DESVENLA FAXINE ER	Must have a paid claims history of one of the
(desvenlafaxine er)	following:
	 mirtazapine, nefazodone, citalopram,
	escitalopram, fluoxetine, fluvoxamine,
	paroxetine, sertraline, duloxetine, venlafaxine,
	OR bupropion
DEXILANT (dexlansoprazole)	Must have a paid claims history of one of the
	following:
	 lansoprazole
	omeprazole
	 pantoprazole
ECOMERRAZOLE	
ESOMEPRAZOLE	Applies only to the Employer Group Formulary
STRONTIUM (esomeprazole	Applies only to the Employer Group Formulary Must have a paid claims history of two of the
	Applies only to the Employer Group Formulary Must have a paid claims history of two of the following:
STRONTIUM (esomeprazole	Applies only to the Employer Group Formulary Must have a paid claims history of two of the following: • lansoprazole
STRONTIUM (esomeprazole	Applies only to the Employer Group Formulary Must have a paid claims history of two of the following:

Drug Name	Step Therapy Criteria
FETZIMA (levomilnacipran)	Must have a paid claims history of one of the
_	following:
	 mirtazapine, nefazodone, citalopram,
	escitalopram, fluoxetine, fluvoxamine,
	paroxetine, sertraline, duloxetine, venlafaxine,
	OR bupropion
FORFIVO XL (buproprion hcl)	Applies to all formularies except the Cal
	MediConnect Drug List
	Must have a paid claims history of one of the
	following:
	 mirtazapine, nefazodone, citalopram,
	escitalopram, fluoxetine, fluvoxamine,
	paroxetine, sertraline, duloxetine, venlafaxine,
	OR bupropion
KHEDEZLA (desvenlafaxine	Must have a paid claims history of one of the
sustained release)	following:
	 mirtazapine, nefazodone, citalopram,
	escitalopram, fluoxetine, fluvoxamine,
	paroxetine, sertraline, duloxetine, venlafaxine,
	OR bupropion
NEXIUM (esomeprazole)	Applies only to the Employer Group Formulary
	Must have a paid claims history of two of the
	following:
	lansoprazole
	omeprazole
	pantoprazole
PEXEVA (paroxetine mesylate)	Applies to all formularies except the Cal
	MediConnect Drug List
	Must have a paid claims history of one of the
	following:
	 mirtazapine, nefazodone, citalopram,
	escitalopram, fluoxetine, fluvoxamine,
	paroxetine, sertraline, duloxetine, venlafaxine,
PRISTIO (desvenlafaxine	OR bupropion Must have a paid claims history of one of the
succinate)	following:
succindite/	 mirtazapine, nefazodone, citalopram,
	 mirtazapine, nerazodone, citalopram, escitalopram, fluoxetine, fluvoxamine,
	paroxetine, sertraline, duloxetine, venlafaxine,
	OR bupropion
TANZEUM (albiglutide for soln	Applies to all formularies except the Cal
non-injector)	MediConnect Drug List
pen-injector)	MediConnect Drug List Must have a paid claims history of:



Step Therapy – Health Net (continued)

Drug Name	Step Therapy Criteria
VENLAFAXINE ER (venlafaxine er)	Must have a paid claims history of one of the following: • mirtazapine, nefazodone, citalopram, escitalopram, fluoxetine, fluvoxamine, paroxetine, sertraline, duloxetine, venlafaxine, OR bupropion
VICTOZA (liraglutide)	Must have a paid claims history of: • metformin HCL
VIIBRYD (vilazodone hcl)	Must have a paid claims history of one of the following: • mirtazapine, nefazodone, citalopram, escitalopram, fluoxetine, fluvoxamine, paroxetine, sertraline, duloxetine, venlafaxine, OR bupropion
ZEGERID (omeprazole-sodium bicarbonate powd pack for susp 20-1680 mg).	Applies only to the Employer Group Formulary Must have a paid claims history of two of the following: Iansoprazole pantoprazole



Express Scripts Medicare – Value Plan

HIGH RISK MEDICATIONS - LONG ACTING

SULFONYLUREAS

Products Affected

Step 2:

- glyburide 1.25 mg tablet
- glyburide 1.25 mg-metformin 250 mg tablet
- glyburide 2.5 mg tablet
- glyburide 2.5 mg-metformin 500 mg tablet
- glyburide 5 mg tablet
- glyburide 5 mg-metformin 500 mg tabl
- glyburide micronized 1.5 mg tablet
- glyburide micronized 3 mg tablet
- glyburide micronized 6 mg tablet

HIGH RISK MEDICATIONS - SEDATIVE HYPNOTICS

Products Affected

Step 2:

- eszopiclone 1 mg tablet
- eszopiclone 2 mg tablet
- eszopiclone 3 mg tablet
- zaleplon 10 mg capsule
- zalepion 5 mg capsule
- zolpidem 10 mg tablet

Details

- zolpidem 5 mg tablet
- zolpidem ER 12.5 mg tablet,extended release,multiphase
- zolpidem ER 6.25 mg tablet,extended release,multiphase

	Details	
Details Criteria If the patient has tried a step 1 drug, the authorization for a Step 2 drug may be given. This step therapy program applies to new utilizers aged greater than 64 years only. Authorization may be given for a Step 2 drug if the patient is currently taking (or has taken in the past) the requested agent.		If the patient has tried a Step 1 drug, then authorization for a Step 2 drug may be given. This step therapy program applies to chronic utilizers greater than 64 years of age only. Authorization for zolpidem or zolpidem Er (brand or generic) may be given if being used for neuroleptic induced parkinsonism, dystonia, restless leg syndrome, or supranuclear paralysis. Authorization for a step 2 drug may be given in patients aged less than 65 years.

- Look back period not designated
- Applies only to new utilizers
- One Step 1 drug needs to be tried prior to Step 2 drug



Express Scripts Medicare – Choice Plan

HIGH RISK MEDICATIONS - SEDATIVE HYPNOTICS

Products Affected

Step 2:

- eszopiclone 1 mg tablet
- eszopiclone 2 mg tablet
- eszopiclone 3 mg tablet
- Lunesta 1 mg tablet
- Lunesta 2 mg tablet
- Lunesta 3 mg tablet
- zaleplon 10 mg capsule

- zaleplon 5 mg capsule
- zolpidem 10 mg tablet
- zolpidem 5 mg tablet
- zolpidem ER 12.5 mg tablet,extended release,multiphase
- zolpidem ER 6.25 mg tablet,extended release,multiphase

- Lunesta 1, 2, and 3 mg tablets included in Step 2 drug list

Details

Criteria	If the patient has tried a Step 1 drug, then authorization for a Step 2 drug may be given. This step therapy program applies to chronic utilizers greater than 64 years of age only. Authorization for zolpidem or zolpidem Er (brand or generic) may be given if being used for neuroleptic induced parkinsonism, dystonia, restless leg syndrome, or supranuclear paralysis. Authorization for a step 2 drug may be given in patients aged less than 65 years.



Group Health Medicare Advantage HMO & PPO

Drug Name	Step Therapy Criteria
SYMBICORT (BUDESONIDE- FORMOTEROL)	A TRIAL MOMETASONE/FORMOTEROL (DULERA) AND FLUTICASONE/SALMETEROL (ADVAIR) WITHIN THE PAST 180 DAYS.
ADVAIR DISKUS ADVAIR HFA (FLUTICASONE- SALMETEROL)	A TRIAL OF MOMETASONE/FORMOTEROL (DULERA) WITHIN THE PAST 180 DAYS.
DIABETA GLUCOVANCE GLYBURIDE GLYBURIDE MICRONIZED GLYBURIDE-METFORMIN HCL GLYNASE (GLYBURIDE)	A TRIAL OF GLIPIZIDE OR GLIMEPIRIDE WITHIN THE PAST 180 DAYS.



Group Health Medicare Advantage HMO & PPO (continued)

DETROL DETROL LA DITROPAN XL ENABLEX GELNIQUE MYRBETRIQ OXYTROL SANCTURA TOVIAZ VESICARE (PREFERRED ANTISPASMODICS)	A TRIAL OF TWO OF THE FOLLOWING URINARY ANTISPASMODICS (OXYBUTYNIN, TOLTERODINE, AND TROSPIUM) IN THE PAST 180 DAYS.	-	Look Back Period = 180 days
JANUMET JANUMET XR JANUVIA KAZANO KOMBIGLYZE XR NESINA ONGLYZA OSENI (PREFERRED DPP-4)	A TRIAL OF LINAGLIPTIN (TRADJENTA) OR LINAGLIPTIN/METFORMI N (JENTADUETO) WITHIN THE PAST 180 DAYS.		



Medi-Cal – Step Therapy Drugs

The following are therapeutic drugs subject to Step Therapy:

Note: It is the intent of the Department of Health Care Services (DHCS) to allow claims for COX-2 inhibitors for patients with a diagnosis of rheumatoid arthritis to pay without meeting any of the clinical exceptions described below or first requiring the use of two Step 1 drugs. Due to system limitations, this will not happen on the December 1, 2004 implementation date. As soon as the Medi-Cal system is updated, providers will be notified.

Category	Step 1	Step 2	Clinical Exceptions
Selective COX-2 Inhibitors Code 1: Arthritis A diagnosis code must be submitted on a pharmacy claim using ICD-9-CM codes 714.xx, 715.xx or 720.xx Note: A patient must try at least two Step 1 drugs before receiving a Step 2 drug.	Diclofenac Sodium * Etodolac Fenoprofen * Ibuprofen * Indomethacin * Ketoprofen * Meclofenamate Sodium Mefenamate Meloxicam * Nabumetone * Naproxen Sodium Naproxen * Oxaprozin Piroxicam * Sulindac * Tolmetin * * These drugs are currently covered under the Medi-Cal List of Contract Drugs and should be used first, if	Celecoxib Valdecoxib	 Beneficiaries with one of the following: age ≥ 65 years a history of ulcer concurrent use of oral corticosteroids concurrent use of anticoagulants rheumatoid arthritis (ICD-9-CM code 714.xx)
	should be used first, if possible.		

 Look back period = 120 days

 Two Step 1 drugs need to be used prior to receiving a Step 2 drug

Note: Patients currently receiving a COX-2 Inhibitor, and have a paid claim within the last 120 days, may continue to receive their medication.



BlueCross BlueShield of North Carolina

- Look Back Period = 90 days, 365 days
- Differences in Age (Muscle relaxant ≥65 yo VS Topical NSAID ≥75 yo)

Stop Thoropy Group	Drug Name	Criteria
Step Therapy Group	Drug Name	
ATOPIC DERMATITIS ST	ELIDEL Tacrolimus Ointment	Criteria for approval require ONE of the following: 1. Patient's medication history includes evidence of a claim within the past 365 days for any topical corticosteroid or topical corticosteroid combination preparation OR 2. Patient has a documented intolerance, ineffective treatment response, FDA labeled contraindication, or hypersensitivity to topical corticosteroids or topical corticosteroid combination preparations
MUSCLE RELAXANT ST	Cyclobenzaprine 5 mg, 7.5 mg, 10 mg tablet Methocarbamol 500 mg, 750 mg tablet	 Step Therapy does NOT apply to patients less than 65 yrs of age. Criteria for approval require ONE of the following: 1. Patient's medication history includes evidence of a claim within the past 90 days for generic tizanidine, generic baclofen, or prescription generic oral NSAID (non-steroidal anti-inflammatory drug) product OR 2. Patient has a documented intolerance, ineffective treatment response, FDA labeled contraindication, or hypersensitivity to generic tizanidine, generic baclofen, or prescription generic baclofen, or prescription generic oral NSAID product
TOPICAL NSAID ST	VOLTAREN GEL	 Criteria for approval require ANY ONE of the following: 1. Patient is 75 years of age or older OR 2. Patient's medication history includes evidence of a claim within the past 90 days for a prescription generic oral NSAID (non-steroidal anti-inflammatory drug) OR 3. Patient has a documented intolerance, ineffective treatment response, FDA labeled contraindication, or hypersensitivity to a prescription generic oral NSAID



Drug Request Form - Definition

- A type of appeal in which a physician submits a form requesting that a Step 2 drug be used for the patient
- Scenarios in which a Drug Request Form is completed?
 - Patient has tried a Step 1 drug and therapy was not effective
 - Physician feels that Step 1 drug will not benefit patient and wants to start the patient directly on Step 2 drug
 - The patient has an FDA-labeled contraindication, intolerance, and/or hypersensitivity to the Step 1 drug
- Usually includes patient information (diagnosis), physician information, and physician's rationale
- May be submitted electronically



Example of Drug Request Form

STEP THERAPY DRUG REQUEST FORM

(Incomplete form may delay processing)

Physician Name:	Prescriber I	nformation		Patient Information
Physicial Name.		NPI#:	Patient Name:	
Office Contact Person:		I	Patient ID # :	
Office Phone # :	Office Fa	x#:	Home Phone # :	
Address:			Sex (circle): M F	DOB:
City:	State: Z	ip:		
	FORM CANNOT	BE PROCESSED V	VITHOUT REQUIRED EXPLAN/	ATION
NOTE: Information on Step	Therapy criteria ca	n be found at <u>http://ww</u>	ww.bcbsnc.com/content/medicare/me	ember/bolicies/approval.htm,
	equisité médicati	on in that class, OR	escriber certification that the men the patient has a documented in	
ATOPIC DERMATITIS	AGENTS			
STEP 2 ATOPIC DERMA	anna Adear a	cortice	red: Indicate the <u>formulary Step</u> ssteroid or topical corticosteroid o patient, or provide an explanation	combination(s) previously taken
MUSCLE DELAYANT	Le this patient	EE waars of ann or	older2 - VEC - NO	
			older? a YES a NO	f (percent) attal percente
MUSCLE RELAXANTS STEP 2 MUSCLE RELAX Cyclobenzaprine Methocarbamol		d: Requi	older? o YES o NO Ired: Indicate the <u>formulary Step</u> line. baclofen or prescription oral titent, or provide an explanation:	
STEP 2 MUSCLE RELAX	XANT Requeste	d: Requi	red: Indicate the <u>formulary Step</u> line. baciofen or prescription oral titent, or provide an explanation:	
STEP 2 MUSCLE RELAX Cyclobenzaprine Methocarbamol	XANT Requeste	d: Requi tizank the pa t 75 years of age or Requi presci	red: Indicate the <u>formulary Step</u> line. baciofen or prescription oral titent, or provide an explanation:	NSAID(s) previously taken by
STEP 2 MUSCLE RELAX	Is this patien D Requested:	d: Requi tizanic the pa t 75 years of age or Requi presci an exp the above-reference	Indicate the <u>formulary Step</u> line. baciofen or prescription oral titent, or provide an explanation: older?	<u>NSAID(s)</u> previously taken by <u>1 (prerequisite) generic</u> aken by the patient, or provide least one Step 1 prerequisite

BlueCross BlueShield of North Carolina



Application to Pharmacy

Doctor prescribes medication that requires Step Therapy

Message is sent to pharmacy's computer Pharmacist is informed that the patient must try a different, similar, firstline medication covered by the plan

Pharmacist calls doctor to get Rx for new drug Doctor may approve OR disapprove order for new drug If doctor disapproves, doctor completes PA and submits to insurance company seeking the use of original drug

If PA is denied, there's an appeal process available if needed





- Step Therapy is a multi-step, type of prior authorization procedure in which a cheaper drug is used prior to a more expensive alternative, provided that the former drug possesses the same clinical benefit to the patient as the more expensive drug.
- Common Step Therapy criteria include medications in the following areas: ADHD, Allergy, Gastrointestinal, Depression, Hypertension, and Pain Management.
- Physicians often complete Drug Request Forms when they would like a Step 2 drug to be covered by the insurance company.



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Thank You for Your Attention

Any Questions?



