Beneficiary Advisory Panel Handout

Uniform Formulary Decisions 9 January 2014

Purpose: The purpose of this handout is to provide the BAP members with a reference document for the clinical effective presentation for each Uniform Formulary (UF) decision.

Short Acting Beta Agonists (SABAs) Metered Dose Inhalers.

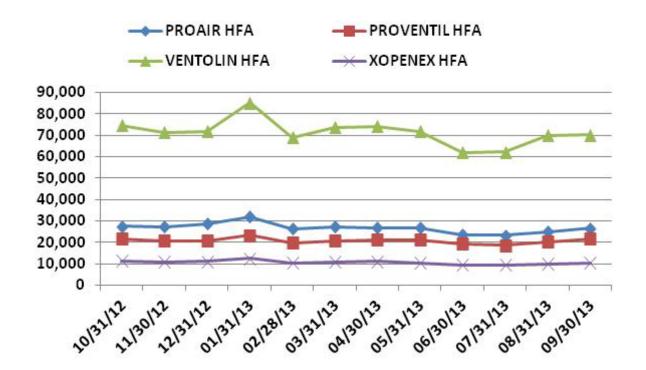
Formulary Agent: ProAir HRA brand of albuterol HFA.

Non-formulary Agents: Proventil HFA and Ventolin HFA brands of albuterol HFA; levalbutrerol HFA (Xoponex HFA).

Number of affected patients: 184,205.

Recommended Implementation Period: 90 days.

Figure 1: Short Acting Beta Agonist Medication Utilization in 30-day Equivalents at All Points of Service



Benign Prostatic Hyperplasia (BPH) Drugs – 5-Alpha Reductase Inhibitors (5-ARIs).

Formulary Agent (step-preferred): finasteride (Proscar generic).

Non-formulary Agents (non step preferred): dutasteride (Avodart); dutasteride/tamsulosin (Jalyn).

Prior Authorization recommended for all new and current users of Avodart, and for all new users of Jalyn.

Prior Authorization:

Avodart: Trial of finasteride required prior to using Avodart, unless:

- -Use of finasteride is contraindicated.
- -Patient has experienced or is likely to experience significant adverse effects from finasteride.

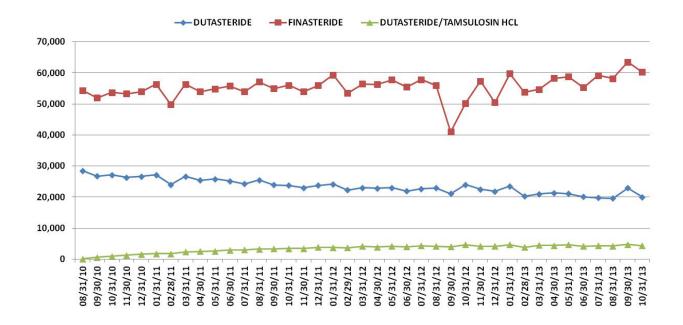
Jalyn: Trial of finasteride required prior to using Jalyn in all new users unless

- Use of finasteride is contraindicated and the patient requires therapy with both an alpha 1 blocker and a 5 ARI.
- Patient has tried finasteride and was unable to tolerate it due to adverse effects, and requires therapy with both an alpha 1 blocker and a 5 ARI.
- Patient is unable to take finasteride (due to a contraindication or adverse events), requires therapy with both an alpha 1 blocker and a 5 ARI, and requires a fixed dose combination, due, to for, example swallowing difficulties.

Recommended Implementation Period: 60 days.

Number of affected patients: 21,000 (for step therapy); 4,700 for non formulary decision.

Figure 2: 5 alpha reductase inhibitor Medication Utilization in 30-day Equivalents at All Points of Service



Antilipidemic -1s (LIP-1s)

Formulary Agent (step-preferred): atorvastatin, atorvastatin/amlodipine, fluvastatin, lovastatin, pravastatin, simvastatin.

Formulary Agent (non step-preferred): rosuvastatin (Crestor).

Non-formulary Agents (non step preferred): simvastatin/ezetimibe (Vytorin), atorvastatin/ezetimibe (Liptruzet), pitavastatin (Livalo), fluvastatin ER (Lescol XL), lovastatin ER (Altoprev), simvastatin/Niaspan (Simcor), lovastatin/Niaspan (Advicor).

Prior Authorization recommended for all new users of Crestor, Vytorin, Liptruzet, Livalo, Lescol XL, Altoprev, Simcor.

Prior Authorization:

Crestor 20 and 40 mg (automated step therapy and manual prior authorization): Trial of a step preferred statin required unless.

- Patient requires a high intensity statin and has tried atorvastatin 40 mg or 80 mg and was unable to tolerate treatment due to adverse effects.
- Patient requires a high intensity statin and is on a concurrent drug metabolized by the cytochrome P 450 3A4 pathway.

Crestor 5 and 10 mg: (manual prior authorization): Trial of a step preferred statin required unless:

- Patient is taking a concurrent drug metabolized by the cytochrome P 450 3A4 pathway and cannot take pravastatin. Provider must document why the patient cannot take pravastatin.
- Patient requires a moderate intensity statin and has tried all 3 of the following drugs atorvastatin greater than 10 mg, simvastatin greater than 20 mg, and pravastatin greater than 40 mg and was unable to tolerate treatment due to adverse effects.

Automated step therapy and manual prior authorization apply to the following:

Vytorin: Patient requires a high intensity statin and has tried atorvastatin greater than 40 mg and was unable to tolerate due to adverse effects.

Vytorin and Liptruzet: Patient requires a high intensity statin and is receiving ezetimibe and simvastatin or atorvastatin separately, and has swallowing difficulties, requiring a fixed dose combination product.

Livalo and Lescol XL: Patient has tried a preferred statin with similar low density lipoprotein lowering effect and was unable to tolerate it due to adverse effects, or the patient is taking a drug that is metabolized by cytochrome P 450 3A4 pathway

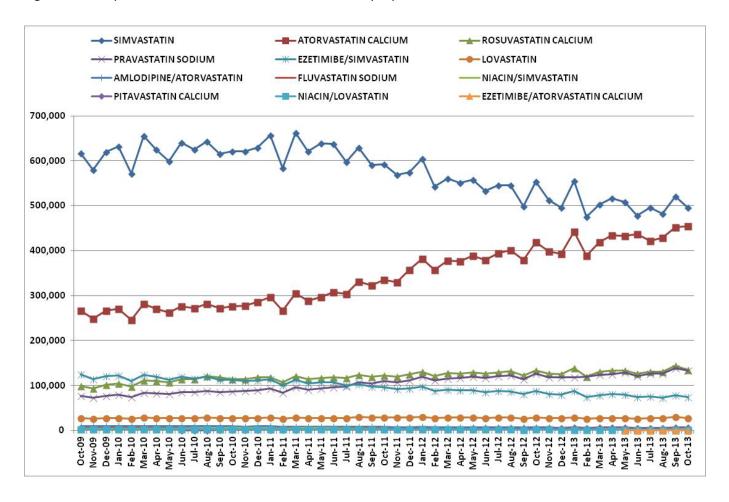
Altoprev: The patient requires treatment with lovastatin 60 mg and cannot take another statin with similar low density lipoprotein lowering effect.

Simcor and Advicor: The patient requires a drug that lowers low density cholesterol and raises high density cholesterol and cannot take two separate tablets, requiring a fixed dose combination product.

Recommended Implementation Period: 60 days.

Number of affected patients: 69,929 (Vytorin), 17,072 (Liptruzet, Livalo, Lescol XL, Altoprev, Simcor, Advicor).

Figure 3: Antilipidemic – 1 Medication Utilization in 30-day Equivalents at All Points of Service



New Drug: Non-Insulin Diabetes Mellitus Drugs (NIDMs) – Dipeptidyl dipeptidase 4 (DPP-4 inhibitors) -alogliptin (Nesina), alogliptin/metformin (Kazano), alogliptin/pioglitazone (Oseni)

Formulary Agents (step preferred): metformin, sulfonylureas (SUs), sitagliptin containing agents

Non-formulary Agents (not step preferred): alogliptin (Nesina), alogliptin/metformin (Kazano), alogliptin/pioglitazone (Oseni)

Prior Authorization recommended for all new and current patients:

Patient has experienced one or more of the following

- metformin:
 - impaired renal function precluding treatment with metformin
 - history of lactic acidosis
- Sulfonylureas:
 - hypoglycemia requiring medical treatment
- patient had inadequate response to step preferred agents
- patient has contraindication to step preferred agents

Recommended Implementation Period: 60 days

Total number of patients affected: 50 (November 2013)

New Drug: Osteoporosis Drugs – Bisphophosphonates – alendronate effervescent (Binosto).

Formulary Agents: alendronate once weekly (Fosamax generics), ibandronate once monthly (Boniva).

Non-formulary Agents: Binosto.

Recommended Implementation Period: 60 days.

Total number of patients affected: 100 (November 2013).

				Patients Affected by Point of Service			Implementation Plan: 1st Wed X	Step Therapy
Meeting	Drug Class	Non-formulary Medication	Total Patients Affected	MTF	Retail	Mail Order	days after decision date	
13-Nov	SABA	Proventil HFA; Ventolin HFA, Xopenex HFA	184,205	~110,000	~55,000	~16,000	90	No
	5-ARI	Avodart; Jalyn	4,700 (formulary decision)	~300	~2,000	~2,400	60	Must try finasteride 1st
	LIP-1s (December interim meeting)	Vytorin, Liptruzet, Livalo, Lexcol XL, Altoprev, Simcor, Advicor	Vytorin 69,929, Others 17,072	V: 34,695; Others: 221	V: 20,443; Others 9,163	V: 14,801; Others 7,688	60	Must try a generic statin with similar LDL reduction 1st
	DPP-4s	Nesina, Kazano, Oseni	50	3	31	16	60	Must try metformin or a sulfonylurea, and a sitagliptin product 1st
	Osteoporosis: Bisphophonates	Binosoto	100	1	67	32	60	No