REMOVING WASTE FROM DRUG FORMULARIES

A practical guide to help employers remove waste from drug formularies and achieve savings for companies and employees while maintaining member satisfaction







This guidebook is the product of a collaboration between the Johns Hopkins Drug Access and Affordability Initiative, the Pacific Business Group on Health and Integrity Pharmaceutical Advisors. The guidebook provides information to plan sponsors encouraging them to identify and remove wasteful drugs from prescription drug formularies.

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Authors

Gerard Anderson, Ph.D. Thomas Cordeiro, R.Ph. Mariana Socal, M.D. Ph.D. Lauren Vela, M.B.A.

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For more information, contact Lauren Vela (Ivela@pbgh.org) or Mariana Socal (msocal1@jhu.edu)

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EXECUTIVE SUMMARY

- Drugs can be considered "wasteful" when they cost more but do not provide greater clinical value when compared to similarly effective but less expensive therapeutic alternatives.
- The revenue model where Pharmacy Benefit Managers (PBMs) keep a portion of the spread, rebate, or other fees paid by drug manufacturers creates a financial incentive for PBMs to prefer or allow drugs with high prices and large rebates or large spreads, which often results in having wasteful drugs on the formulary.
- To prevent plan dollars from being wasted, wasteful drugs should be excluded from coverage rather than placed in a higher cost-sharing tier or (with some exceptions) having prior authorization or step therapy.
- A comprehensive communication strategy regarding formulary or plan changes will serve to inform members of the impending improvements and ease member and prescribing physicians' transitions.
- Member satisfaction can be maintained while removing wasteful drugs because the formulary will still
 cover equally effective, or even more effective drugs, at lower prices and employees have become
 increasingly accustomed to formulary changes
- The universe of drugs that can be considered wasteful is very large. However, analysis of large employers' drug claims has shown that few drugs may account for much of the savings, depending on the company's utilization pattern. An empirical example of potential savings is provided in this guide.
- All plan sponsors should check if their drug formularies contain wasteful drugs. A brief demonstration list of wasteful drugs is provided in this guide.
- In order to successfully remove waste from drug formularies, plan sponsors should make sure that their contracts with PBMs have three core attributes: fee-based (i.e., full pass-through) model, transparency (full audit rights) and formulary flexibility.
- Given the need to evaluate the clinical value of drugs, and given the very complicated pricing structure within the pharmaceutical supply chain, it is likely that specialized, independent consultants, will be required. It is important to have non-conflicted independent consultants to assure objectivity and alignment with the plan sponsor.
- The success of a waste-free formulary can be measured in two ways: the savings obtained by the employer and the satisfaction provided to employees.
- There are challenges associated with removing wasteful drugs from formularies that many companies have addressed. A list of obstacles, as well as potential strategies to overcome them, is provided in this guide.

1. IDENTIFYING WASTEFUL DRUGS

What are "wasteful" drugs?

Wasteful drugs are those drugs which don't provide additional clinical value when compared to other drugs that are used for the same condition which are less expensive.

While hundreds of such drugs exist, many can be grouped into four basic categories, which are summarized in the box

Why wasteful drugs are included on formularies

Pharmacy Benefit Managers (PBMs) negotiate discounts and rebates with drug manufacturers in return for favorable formulary placement. When PBMs keep a portion of the rebate and/or other fees paid by the manufacturer, it creates an incentive for PBMs to prefer highly rebated drugs on their formularies, even if these drugs don't provide the best value.

In addition, PBMs may earn a "spread", which is the difference between what the PBMs pay the pharmacies and what the PBMs are reimbursed by employers. The revenue garnered from the spread is larger for higher-priced drugs, therefore spread pricing incentivizes PBMs to have higher-priced drugs in the formulary.

Both Branded and Generic Drugs Can

Be Wasteful. There is a financial incentive for PBMs to prefer drugs with high prices and large rebates or large spreads, which often results in having wasteful drugs on the formulary.

MAIN CATEGORIES OF WASTEFUL DRUGS

- Multi-Source drugs: high-cost branded or generic products when less expensive generics are available
- Fixed-Dose Combination ("Combo Drugs"): drugs with two or more active ingredients in one pill costing substantially more than the individual ingredients in separate pills
- Drugs for which over-the-counter (OTC) options are available
- Me-too drugs: immaterial tweaking of a particular ingredient results in a "new" more expensive drug that adds no clinical value as compared to the less expensive original version.

Why wasteful drugs should be excluded (not tiered or "managed")

More expensive drugs can be placed on high cost-sharing tiers, which is intended to discourage patients from using them. However, drug manufacturers may provide coupons and discount cards to encourage patients to use these more expensive drugs. When a coupon is used, it eliminates or reduces the patient's cost-sharing responsibility, but the cost of the wasteful drug is still paid by the employer.

Efforts to institute higher cost-sharing as a means to discourage the use of wasteful drugs will be nullified if patients obtain drug coupons from their doctors, pharmacists, online, or by contacting a manufacturer. To prevent plan dollars from being wasted, wasteful drugs need to be excluded from coverage rather than placed in a higher cost-sharing tier.

To prevent plan dollars from being wasted, wasteful drugs need to be excluded from coverage rather than placed in a higher cost-sharing tier.

Utilization controls such as prior authorization and step therapy are not adequate means of guarding against wasteful drug spending in most cases because those strategies are only as effective as the clinical criteria that they follow. Utilization controls can become a simple matter of "checking the box" and may not discourage the use of wasteful drugs.

In addition, clinical criteria and their application are not readily auditable, making it harder to assess their true impact.

Excluding wasteful drugs from the formulary can also be advantageous to patients, because it protects them from unnecessarily higher spending. Patients will not be negatively impacted by the exclusion of wasteful drugs because the formulary will still cover equally or even more effective drugs, at lower prices. Wasteful drugs should rightfully be excluded from formularies, and many companies have already moved in this direction (Appendix 1).

2. HOW MUCH CAN BE SAVED BY REMOVING WASTEFUL DRUGS FROM FORMULARIES?

Estimating savings: unit cost discounts vs. total savings

When excluding a wasteful drug, the formulary should cover one or more alternatives that are equally or more effective than the wasteful drug, at lower prices.

Although some wasteful drugs can cost 50 to 100 times more per unit than their therapeutic alternatives, the total savings obtained from removing a wasteful drug from the formulary will vary from company to company depending on the drug utilization. For example, removing a wasteful drug that is used very frequently may provide great savings even if the alternative drug is only moderately less expensive.

Experience from 15 employers

An analysis of 6 months of drug utilization of 15 large self-insured plan sponsors was performed by the Pacific Business Group on Health and Integrity Pharmaceutical Advisors.¹ They examined more than 2.5 million scripts and found that **6% of all drug claims were for wasteful drugs**.

Wasteful drug claims represented 3-24% of companies' total spend on drug benefits, depend-



PBGH/Integrity Study Savings

8 drugs accounted for 21% of all savings

ing on which drugs were included in the formulary and how often they were utilized. In this analysis, 8 drugs accounted for 21% of the savings (see Figure). However, this is only the "tip of the iceberg," as there are more than 800 drugs on the market today that can be considered wasteful.

"We were very mindful of employee disruption but found that there was much less 'noise' than expected. We attribute this to the fact that the vast majority of physicians are comfortable with changing scripts to our formulary because the drugs we cover are safe and just as effective as the ones that have been excluded."

-JOHN STENERSON, DEPUTY EXECUTIVE OFFICER, SELF-INSURED SCHOOLS OF CALIFORNIA (SISC)

¹ Vela, L. Reducing Wasteful Spending in Employers' Pharmacy Benefit Plans. The Commonwealth Fund. Issue Brief, August 2019. https://www.commonwealthfund.org/publications/issue-briefs/2019/aug/reducing-wasteful-spending-employers-pharmacy-benefit-plans

3. HOW EMPLOYERS CAN SUCCESSFULLY REMOVE WASTEFUL DRUGS FROM THEIR FORMULARIES

STEP 1.

Identify wasteful drugs using a demonstration list

Physicians and pharmacists from Johns Hopkins University, Integrity Pharmaceutical Advisors, and Pacific Business Group on Health partnered to develop a list of wasteful drugs (Appendix 2). This list can be used to request an output report from PBMs or consultants to identify wasteful drugs and evaluate opportunities for savings. An example of savings output report is provided in Appendix 3.

The universe of drugs that can be considered wasteful – currently estimated to contain more than 800 drugs – is much larger than the drugs presented on this list. While drugs on this demonstration list only represent a fraction of the savings opportunity, they can serve to identify whether a plan's formulary is permitting wasteful drug utilization.

STEP 2.

Eliminate wasteful drugs though better contracting with PBMs

Three contractual approaches that companies should consider to reduce waste are:

1) FEE-BASED MODEL (Full pass-through model)

In a full pass-through model, 100% of rebates and all other manufacturer payments are passed in full by the PBM to the employer or employee. Payments can include all monies classified as rebates, but can also include all other monies paid by the drug manufacturer to the PBM, such as: formulary administrative fees, remuneration discounts, inflation protection payments, marketing fees, distribution fees, handling fees, promotional fees, and any other fee garnered from the drug manufacturer to the PBM regardless of its name.

A full pass-through model is an administra-

tive fee-based model. The PBM obtains revenue exclusively from the fees charged to the employer. There are no hidden charges. This enables the purchaser to know exactly what they are paying for their intermediaries' services and better evaluate the value proposition of the PBM. This model effectively eliminates incentives for the PBM to include wasteful drugs on the formulary.

2) TRANSPARENCY

Transparency is an essential element when evaluating PBM value and performance. Transparency, in this instance, means the PBM's contract with the plan sponsor allows the plan sponsors full access to their own utilization and spending data as well as the ability to audit all of the contracts between the PBM and pharmacies and between the PBM and drug manufacturers. This level of transparency is necessary to ensure that a full pass-through business model is being administered. It should be concerning that some PBMs do not allow this level of transparency.

3) FORMULARY FLEXIBILITY

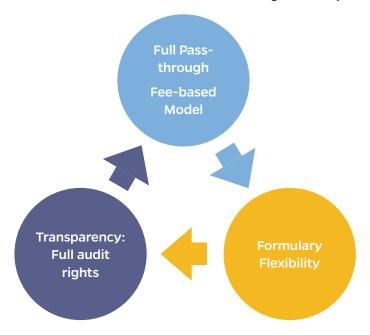
Plan sponsors will need the flexibility to customize the formulary and clinical programs in order to meet the unique needs of their beneficiaries. As with transparency, this flexibility needs to be included as part of the plan sponsor's rights in the contract between the plan sponsor and the PBM.

STEP 3.

Achieve Success: Savings & High Member Satisfaction

The success of a waste-free formulary can be measured in two ways: the savings obtained (by the plan sponsor and plan members) and the satisfaction of the employees.

Figure. Attributes of PBM Contracts That Are Essential for Removing Wasteful Spending



Using consultants

Given the need to evaluate the clinical value of drugs, and given the very complicated pricing structure within the pharmaceutical supply chain, it is likely that specialized, independent consultants will be required. It is important to have non-conflicted independent consultants to assure objectivity and alignment with the plan sponsor. Health plans, PBMs, and the consultants that represent drug collaboratives or that offer shared savings arrangements may be influenced by the misaligned incentives and revenue streams that contribute to having wasteful drugs on the formularies.

"Independent and non-conflicted consultants are 'worth their weight' in gold".

-JANET FARABAUGH, SR. DIRECTOR OF GLOBAL BENEFITS AT SEAGATE TECHNOLOGY

Maintaining high member satisfaction

A comprehensive communication strategy regarding formulary or plan changes will inform members of the impending changes and ease member and prescribing physicians' transitions. It is possible to "grandfather" select drugs, drug classes or patients to make changes for new prescriptions only. Be prepared to supply clinical justification via links or articles for suggested alternative equally effective drugs. A concierge service can help mitigate the impact of the formulary changes by engaging providers to proactively adjust prescriptions.

$\mathsf{APPENDIX}\ 1.\ \mathbf{Anticipating\ Challenges\ and\ Mitigating\ Them}$

There are challenges associated with removing wasteful drugs from formularies that other companies have addressed. Major obstacles, as well as potential strategies to overcome them, are outlined below.

Table. Obstacles to Achieving a Waste-Free Formulary and Some Strategies to Mitigate Them

Identify Obstacles	Address Obstacles
PBMs may refuse to remove certain drugs from the formulary.	 If a PBM does not want to eliminate a drug from the formulary, it is likely because they are earning a profit on that drug Insist on the right to customize the formulary to eliminate "wasteful drugs" Move to a "pass-through model" which assures that the PBM does not earn profits from rebates or other manufacturer fees to PBMs.
PBMs increase their administrative fees when they eliminate wasteful drugs from the formulary.	 Compare the expected TOTAL per member per month, (PMPM) cost that includes administrative fees and drug costs minus rebates. Insist on a PMPM estimate. PMPM is a more reliable benchmark. It is what you pay. Conventional consultants use procurement spreadsheets that limit analysis to comparisons of administration fees, rebate guarantees, and discounts, which overlook the added value of transparency and flexibility and can therefore be misleading. Employer experience confirms that savings from removing wasteful drugs will be greater than the increased administrative fees and the reduced rebates.
Rebate amounts will be smaller with a low net cost formulary.	◆ PBMs return some portion of the rebates to the employer. While large rebate checks may seem appealing, costs are much higher to access them, savings produced from removing wasteful drugs are greater than the lost revenue from rebates.
Consultants may have conflicts because they may also derive revenues from drug utilization.	 Make sure that any PBM consultant is NOT receiving ANY revenues from PBMs or pharmaceutical manufacturers. Assure this via contractual arrangement. Estimate consultant fees as a component of the PMPM. Some consultants might offer a shared savings arrangement. A straightforward payment for services (fee-based model) is always preferable because it leaves no wiggle room for misaligned incentives. Employers report that independent consultants generate substantial return on investment when they eliminate wasteful spending.
OTC drugs may cost less than beneficiaries' copay or coinsurance.	Consider covering select over-the-counter (OTC) drugs so that patients' cost- share and total plan spending will be aligned with the lowest cost option.
Concern for member satisfaction	 Patients are ever more accustomed to formulary changes Provide adequate notice to make the change (consider 90 days) Communicate to employees about plan savings (and personal savings to them) by eliminating wasteful drugs. Be prepared to supply clinical justification via links or articles for the therapeutic alternatives covered in the formulary. Consider "grandfathering" some drugs and making changes for new prescriptions only. Consider contracting with a clinical concierge vendor to assist patients and prescribing doctors and assure a smooth transition

$\text{APPENDIX 2.} \ \, \text{Demonstration List of Wasteful Drugs, Less Expensive Therapeutic Alternatives, and Per-Unit Savings Potential}$

- ♦ The table compares high-cost wasteful drugs with their less expensive therapeutic alternatives.
- The large difference between the prices of the wasteful drugs and the therapeutic alternatives indicates that, even when discounts and rebates are accounted for, the therapeutic alternative will still offer savings as compared to the wasteful drug.
- The total savings obtained from removing each wasteful drug from the formulary will depend on the utilization levels. Removing a wasteful drug with high utilization may provide great savings even if the price of its therapeutic alternative represents a low per-unit discount.
- ♦ A list of NDCs corresponding to the wasteful drugs below can be obtained at http://www.pbgh.org/druglistndc or by request to the authors.

В	and Name & Active Ingredient	Main Indication	Unit Price
М	ulti-Source drugs: high-cost branded or generic di	rugs for which less expensive options are	available
1	Gleevec (imatinib)	Leukemia and gastrointestinal tumors	\$112.37
2	Auvi-Q (epinephrine auto-injector)	Acute allergic reactions	\$2,940.00
3	Penlac External (ciclopirox solution 8%)	Toenail fungus	\$204.93
4	Carafate 1g tablets	Duodenal ulcer, short term treatment	\$4.88
5	Vanos External (Fluocinonide 0.1% cream)	Itching of the skin (Pruritus)	\$32.82
6	Prenate (prenatal multivitamins) - multiple preparations e.g., Prenate DHA, Prenate Star, et	Nutritional supplement for pregnancy	\$9.19
7	Nexium Capsule Delayed Release (esomeprazole magnesium)	Gastroesophageal reflux disease	\$10.04
9	Fixed-Dose Combination ("Combo Drugs"): drugs was the substantially higher than the individual ingredients for which over- the-counter (OTC) options		_
3	Duexis (ibuprofen + famotidine)	Pain in osteoarthrosis and arthritis	\$33.10
9	Vimovo (Naproxen + esomeprazole)	Pain in osteoarthrosis and arthritis	\$49.64
10	Zegerid (Omeprazole + Sodium bicarbonate)	Gastroesophageal reflux disease	\$132.27
	Percocet (Oxycodone + acetaminophen)	Acute Pain	\$28.10
LI	· · · · · · · · · · · · · · · · · · ·	/ teate i aiii	\$20.10
L2 N	Primlev (Oxycodone + acetaminophen) le- too drugs: immaterial tweaking of a particular rug that adds no clinical value as compared to the	Acute Pain ingredient results in a "new" more expensiless expensive original version.	\$22.10
12 N d	Primlev (Oxycodone + acetaminophen) le- too drugs: immaterial tweaking of a particular rug that adds no clinical value as compared to the cample 1: Difference in the salt or chemical form of	Acute Pain ingredient results in a "new" more expensiess expensive original version. the active ingredient	\$22.10 sive drug
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12 M d E) 13 14 E) 15 16 17 18 19 20 21 E) 22 23	Primlev (Oxycodone + acetaminophen) Ne- too drugs: immaterial tweaking of a particular rug that adds no clinical value as compared to the cample 1: Difference in the salt or chemical form of Dexilant (dexlanzoprazole) Aplenzin (bupropion hydrobromide) cample 2: Difference in the formulation: cream vs. In Xilapak (fluocinolone acetonide solution kit 0.01%) Clodan External (Clobetasol propionate kit 0.05%) Generic adapalene - Pads 0.1% Generic adapalene - Solution 0.1% Cambia (diclofenac 50mg packets) Carafate 1g/10ml suspension Generic lactulose 10gram packet cample 3. Difference in the absorption speed: extent Glumetza (Extended-Release Metformin)	Acute Pain ingredient results in a "new" more expensives expensive original version. the active ingredient Gastroesophageal reflux disease Smoking Cessation, Major Depression otion, capsule vs. tablet, packet vs. capsul Itching of the skin (Pruritus) Itching of the skin (Pruritus) Acne Acne Mild to moderate acute pain Duodenal ulcer Constipation ded release vs. immediate release Type II diabetes	\$11.30 \$165.56 e, etc. \$7,341.60 \$639.08 \$105.00 \$18.00 \$90.74 \$6.00 \$59.92
12 N d E 13 14 E 15 16 17 18 19 20 21 E 22 23 24	Primlev (Oxycodone + acetaminophen) Re- too drugs: immaterial tweaking of a particular rug that adds no clinical value as compared to the cample 1: Difference in the salt or chemical form of Dexilant (dexlanzoprazole) Aplenzin (bupropion hydrobromide) cample 2: Difference in the formulation: cream vs. Is Xilapak (fluocinolone acetonide solution kit 0.01%) Clodan External (Clobetasol propionate kit 0.05%) Generic adapalene - Pads 0.1% Generic adapalene - Solution 0.1% Cambia (diclofenac 50mg packets) Carafate 1g/10ml suspension Generic lactulose 10gram packet cample 3. Difference in the absorption speed: extendium closed compared to the absorption closed compared compa	Acute Pain ingredient results in a "new" more expensives expensive original version. the active ingredient Gastroesophageal reflux disease Smoking Cessation, Major Depression otion, capsule vs. tablet, packet vs. capsul Itching of the skin (Pruritus) Itching of the skin (Pruritus) Acne Acne Mild to moderate acute pain Duodenal ulcer Constipation ded release vs. immediate release Type II diabetes Type II diabetes	\$11.30 \$165.56 \$165.56 \$639.08 \$105.00 \$18.00 \$90.74 \$6.00 \$59.92 \$133.60 \$42.17
12 M d 13 14 15 16 17 18 19 20 21 En 22 23 24 25	Primlev (Oxycodone + acetaminophen) Ile- too drugs: immaterial tweaking of a particular rug that adds no clinical value as compared to the cample 1: Difference in the salt or chemical form of Dexilant (dexlanzoprazole) Aplenzin (bupropion hydrobromide) cample 2: Difference in the formulation: cream vs. Iv. Xilapak (fluocinolone acetonide solution kit 0.01%) Clodan External (Clobetasol propionate kit 0.05%) Generic adapalene - Pads 0.1% Generic adapalene - Solution 0.1% Cambia (diclofenac 50mg packets) Carafate 1g/10ml suspension Generic lactulose 10gram packet cample 3. Difference in the absorption speed: extending extended-Release Metformin) Fortamet (Extended-Release Metformin (OSM)	Acute Pain ingredient results in a "new" more expensives expensive original version. the active ingredient Gastroesophageal reflux disease Smoking Cessation, Major Depression otion, capsule vs. tablet, packet vs. capsul Itching of the skin (Pruritus) Itching of the skin (Pruritus) Acne Acne Mild to moderate acute pain Duodenal ulcer Constipation ded release vs. immediate release Type II diabetes Type II diabetes Type II diabetes	\$11.30 \$165.56 \$165.56 \$639.08 \$105.00 \$18.00 \$90.74 \$6.00 \$59.92 \$133.60 \$42.17 \$31.40
12 M d 13 14 15 16 17 18 19 20 21 En 22 23 24 25	Primlev (Oxycodone + acetaminophen) Re- too drugs: immaterial tweaking of a particular rug that adds no clinical value as compared to the cample 1: Difference in the salt or chemical form of Dexilant (dexlanzoprazole) Aplenzin (bupropion hydrobromide) cample 2: Difference in the formulation: cream vs. Idiapak (fluocinolone acetonide solution kit 0.01%) Clodan External (Clobetasol propionate kit 0.05%) Generic adapalene - Pads 0.1% Generic adapalene - Solution 0.1% Cambia (diclofenac 50mg packets) Carafate 1g/10ml suspension Generic lactulose 10gram packet cample 3. Difference in the absorption speed: extent Glumetza (Extended-Release Metformin) Fortamet (Extended-Release Metformin (OSM) Generic Extended-Release Metformin (MOD) Naproxen (Naproxen Sodium Extended Release)	Acute Pain ingredient results in a "new" more expensives expensive original version. the active ingredient Gastroesophageal reflux disease Smoking Cessation, Major Depression otion, capsule vs. tablet, packet vs. capsul Itching of the skin (Pruritus) Itching of the skin (Pruritus) Acne Acne Mild to moderate acute pain Duodenal ulcer Constipation ded release vs. immediate release Type II diabetes	\$11.30 \$165.56 \$165.56 \$639.08 \$105.00 \$18.00 \$90.74 \$6.00 \$59.92 \$133.60 \$42.17 \$31.40 \$120.24

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Demonstration List of Wasteful Drugs, Less Expensive Therapeutic Alternatives, and Per-Unit Savings Potential

The therapeutic alternatives presented below are illustrative and may vary according to differences in patient populations, drug prices, and others.

Less Expensive Therapeutic Alternative					
Th	erapeutic Alternative ²	Unit Price ³	Per-Unit Discount ⁴		
1	Generic Imatinib	\$4.09	96%		
2	Generic Epipen	\$247.01	92%		
3	Generic ciclopirox external solution 8%	\$8.02	96%		
4	Generic Sucralfate 1g tablets	\$0.33	93%		
5	Generic fluocinonide 0.01% cream	\$0.54	98%		
6	PreNata (Chewable tablet	\$0.10	99%		
7	GoodSense Esomeprazole Oral (Capsule, delayed release)	\$0.25	98%		
			·		
8	Generic ibuprofen (OTC) + Generic famotidine (OTC)	\$0.58	98%		
9	Generic naproxen (OTC) + generic esomeprazole (OTC)	\$0.38	99%		
10	Generic omeprazole (OTC) + sodium bicarbonate (OTC)	\$0.60	99.5%		
11	Generic oxycodone (Rx only) + acetaminophen (OTC)	\$1.44	95%		
12	Generic oxycodone (Rx only) + acetaminophen (OTC)	\$1.44	93%		
	Generic lanzoprazole	\$0.30	97%		
14	Generic bupropion hydrochloride	\$16.0	90%		
15	Generic Fluocinolone acetonide cream, 0.01%	\$1.57	99.98%		
16	Clobetasol propionate 0.05% cream	\$1.53	99.8%		
17	Differin gel 0.1%(adapalene OTC)	\$0.56	99%		
18	Differin gel 0.1%(adapalene OTC)	\$0.56	97%		
19	Generic diclofenac 50mg EC tablet	\$0.95	99%		
20	Generic Sucralfate 1g tablets	\$0.33	95%		
21	Generic Lactulose 10 gram/15ml solution	\$0.45	99%		
22	Generic Metformin (regular release)	\$0.08	99.9%		
	Generic Metformin (regular release)	\$0.08	99.8%		
24		\$0.08	99.7%		
25		\$0.08	99.9%		
26	, , ,	\$0.28	98.9%		
27		\$0.28	98.7%		
28		\$6.46	87%		
	.,,	1			

APPENDIX 2 (pg 3 of 4)

Demonstration List of Wasteful Drugs, Less Expensive Therapeutic Alternatives, and Per-Unit Savings Potential

- ◆ The table compares high-cost wasteful drugs with their less expensive therapeutic alternatives.
- The large difference between the prices of the wasteful drugs and the therapeutic alternatives indicates that, even when discounts and rebates are accounted for, the therapeutic alternative will still offer savings as compared to the wasteful drug.
- The total savings obtained from removing each wasteful drug from the formulary will depend on the utilization levels.
 Removing a wasteful drug with high utilization may provide great savings even if the price of its therapeutic alternative represents a low per-unit discount.
- ♦ A list of NDCs corresponding to the wasteful drugs below can be obtained at http://www.pbgh.org/druglistndc or by request to the authors.

w	asteful Drug		
Br	and Name & Active Ingredient	Main Indication	Unit Price ¹
E	xample 4. Difference in the strength or concentration	on (mg)	
29	Venipuncture Px1 Phlebotomy (Lidocaine Kit 2%)	Preparation for venipuncture	\$981.00
30	Lidotral (Lidocaine topical cream 3.88%)	Temporary relief of minor localized pain	\$17.63
31	Generic Lidocaine topical cream 4.12%	Temporary relief of minor localized pain	\$23.32
32	Synalar TS External (fluocinolone acetonide solution kit 0.01%)	Itching of the skin (Pruritus)	\$628.36
33	Zorvolex (diclofenac 35mg capsules)	Mild to moderate acute pain	\$8.67
34	Zipsor (diclofenac capsules 25mg)	Mild to moderate acute pain	\$9.36
35	Generic Hydrocodone and acetaminophen solution 10mg+325mg/15ml	Pain management	\$190.20
36	Generic Hydrocodone and acetaminophen 7.5-300mg tablets	Pain management	\$8.63
37	Generic Hydrocodone and acetaminophen 10-300 mg tablets	Pain management	\$8.63
38	Generic Chlorzoxazone 250mg tablets	Skeletal muscle relaxant	\$24.88
39	Generic Doxycycline 150mg capsules	Bacterial infections	\$24.65
40	Oracea (Doxycycline 40mg delayed-release capsule)	Acne	\$29.56
E	cample 5. Me-too drugs and their therapeutic alterna	atives are different drugs in the same therap	eutic class
41	Edarbi (azilsartan)	Hypertension	\$8.14
42	Edarbycor (azilsartan + hydrochlorothiazide)	Hypertension	\$7.68
43	Lumigan (Bimatoprost 0.01%)	Glaucoma	\$94.51
44	Elocon 0.1% (mometasone furoate cream)	Itching of the skin (Pruritus)	\$232.00
S	pecial Case: Wasteful drugs whose therapeutic alter	natives are drugs in a different therapeuti	c class
45	Jublia (efinaconazole 10%)	Toenail fungus	\$171.85
46	Jublia (efinaconazole 10%)	Toenail fungus	\$171.85
47	Generic Doxepin HCL External Cream 5%	Itching of the skin (Pruritus)	\$722.25
48	Zonalon (Doxepin HCL External Cream 5%)	Itching of the skin (Pruritus)	\$1,066.95
49	Prudoxin External (Doxepin HCL External Cream 5%	Itching of the skin (Pruritus)	\$802.00

Notes:

- 1. Prices correspond to manufacturer-set list prices (Average Wholesale Price AWP) in July 17, 2019 as obtained from Wolters Kluver's LexiComp® (www.online.lexi.com). Prices do not account for discounts and rebates that may be negotiated with drug manufacturers by insurance plans or pharmaceutical benefits managers (PBMs). Unit price represent the cost per pill, kit, tube, milliliter, or gram. Prices provided in this table are merely illustrative, as prices fluctuate over time and may vary significantly across manufacturers, especially in the case of generics and multi-source drugs.
- Multiple products may serve as therapeutic alternatives to the wasteful drugs listed on this table. The therapeutic alternatives provided here were chosen because of their high similarity to the wasteful drug in terms of chemical composition, clinical indications, clinical effectiveness, and safety profiles, as well as their lower price.

APPENDIX 2 (pg 4 of 4)

Demonstration List of Wasteful Drugs, Less Expensive Therapeutic Alternatives, and Per-Unit Savings Potential

The therapeutic alternatives presented below are illustrative and may vary according to differences in patient populations, drug prices, and others.

Th	erapeutic Alternative ²	Unit Price ³	Per-Unit Discount⁴
		·	<u>'</u>
29	Generic Lidocaine Kit 4%	\$30.00	97%
30	Generic Lidocaine topical cream 4%	\$1.68	90%
31	Generic Lidocaine topical cream 4%	\$1.68	93%
32	Synalar (Ointment) External 0.025%	\$1.57	99.8%
33	Generic diclofenac 50mg EC tablet	\$0.95	89%
34	Generic diclofenac 25mg EC tablet	\$1.42	85%
35	Lortab oral (Hydrocodone and Acetaminophen elixir 10+300mg/15ml)	\$7.35	96%
36	Generic Hydrocodone+ acetaminophen 7.5-325mg tablets	\$0.37	96%
37	Generic Hydrocodone+ acetaminophen 7.5-325mg tablets	\$0.46	95%
38	Generic Chlorzoxazone 500mg tablets	\$1.08	96%
39	Generic Doxycyline 50mg capsules (taken 3 capsules)	\$4.35	82%
40	Generic Doxycyline 20mg tablets (taken 2 tablets)	\$1.54	95%
41	Generic valsartan	\$0.09	98.9%
42		\$0.17	97.8%
43	Latanoprost 0.005%	\$6.00	93.7%
44	Generic hydrocortisone 0.25% cream	\$11.25	95%
45	Generic Terbinafine 250mg (oral use)	\$12.67	93%
46	Generic ciclopirox external solution 8% (topical use)	\$8.02	95%
47	Axsain (Capsaicin cream 0.25%)	\$34.20	95%
48	Axsain (Capsaicin cream 0.25%)	\$34.20	97%
49	Axsain (Capsaicin cream 0.25%)	\$34.20	96%

Notes (continued):

- 3. The price of the therapeutic alternative is provided at the same unit corresponding to the wasteful drug. When therapeutic alternatives do not have the same unit as the wasteful drug (for example, when two pills are required to substitute a 1-pill combo drug), the price of the therapeutic alternative was adjusted to represent the number of units needed to adequately substitute the wasteful drug.
- 4. Per-Unit discount rates represent the percentage discount that is offered by the alternative product as compared to the wasteful product at the unit level, calculated as: 1-[unit price of therapeutic alternative/unit price of wasteful drug].

$APPENDIX\ 3$. Savings Output Report - Illustrative Examples

- The examples below demonstrate the savings that can be obtained by employers when substituting a wasteful drug for its therapeutic alternative under a few different scenarios.
- All scenarios are presented for 30-day claims of each drug. Prices provided in these examples are merely illustrative, as prices fluctuate over time and may vary significantly across manufacturers, especially in the case of generics and multi-source drugs.
- Prices reflect total cost per each 30-day claim, and do not break down between plan and member cost-sharing expenditures.

Example 1. ORACEA® (Doxycycline 40mg)						
30-day claims	Nr. units	List Price (AWP) ¹	Discounted Price ² (no rebates)	Price with 42% combined discount & rebate ³	Price with 74% combined discount & rebate ⁴	
Wasteful Drug						
Oracea 40mg (doxycycline 40mg) extended release capsules	30 pills	\$886.80	\$802.07	\$561.45	\$248.60	
Therapeutic Alternative						
Generic Doxycycline 20mg tablets	60 pills	\$46.20	\$26.54	\$26.54	\$26.54	
Savings per 30-day claim at each price		\$840.60	\$775.53	\$534.91	\$222.06	

[%] rebate needed to offset savings—96.7%

Notes:

- 1. Average Wholesale Price (AWP) corresponds to manufacturer-set list prices for a 30-day supply of the drug as obtained from Wolters Kluver's LexiComp® (www.online.lexi.com) in August 15, 2019.
- 2. Discounted Prices represent prices from actual claims from 3rd quarter 2019 from an existing company and do not account for manufacturer rebates.
- 3. 42% represents the average price concessions realized across twelve therapeutic classes in Medicare part D, inclusive of all discounts and rebates, as estimated by the IQVIA institute in October 2016 (see reference below). The IQVIA report examined wholesale acquisition cost (WAC) prices and identified that, on average, the final price of the drug was 35% lower than the WAC. The adjusted rate presented here accounts for the difference between AWP and WAC prices by assuming that AWP represents 1.2 times the WAC (see reference by Curtis et al. below). Price concessions are typically not offered by generic manufacturers and were, therefore, not applied to the generic drugs presented in this example.

APPENDIX 3 (pg 2 of 2) Savings Output Report - Illustrative Examples

- The examples below demonstrate the savings that can be obtained by employers when substituting a wasteful drug for its therapeutic alternative under a few different scenarios.
- All scenarios are presented for 30-day claims of each drug. Prices provided in these examples are merely illustrative, as prices fluctuate over time and may vary significantly across manufacturers, especially in the case of generics and multi-source drugs.
- Prices reflect total cost per each 30-day claim, and do not break down between plan and member cost-sharing expenditures.

Example 2. DUEXIS ® (Ibuprofen + famotidine)						
30-day claims	Nr. units	List Price (AWP) ¹	Discounted Price ² (no rebates)	Price with 42% combined discount & rebate ³	Price with 74% combined discount & rebate ⁴	
Wasteful Drug						
Duexis (Ibuprofen 800mg + Famotidine 26mg)	90 pills	\$2,979.00	\$2,684.78	\$1,721.71	\$832.28	
Therapeutic Alternative						
Ibuprofen 800mg Savings per claim at each price	90 pills	\$16.80 \$2,962.20	\$16.80 \$2,667.98	\$16.80 \$1,704.91	\$16.80 \$815.48	

[%] rebate needed to offset savings—99.39%

Notes (continued):

4.74% represents the maximum price concessions realized across twelve therapeutic classes in Medicare part D, inclusive of all discounts and rebates, as estimated by the IQVIA institute in October 2016 (see reference below). The IQVIA report examined wholesale acquisition cost (WAC) prices and identified that the final price of the drug was at maximum 69% lower than the WAC. The adjusted rate presented here accounts for the difference between AWP and WAC prices by assuming that AWP represents 1.2 times the WAC (see reference by Curtis et al. below). Price concessions are typically not offered by generic manufacturers and were, therefore, not applied to the generic drugs presented in this example.

References:

 $\label{lem:curtiss} \ \ FR, \ Lettrich P, Fairman KA. \ \ What is the price benchmark to replace average wholesale price (AWP)? \ \ J \ \ Manag \ Care Pharm. 2010 \ Sep; 16(7):492-501. \ https://www.ncbi.nlm.nih.gov/pubmed/20726678$

IQVIA – Quintiles/IMS Institute. Estimate of Medicare Part D Costs After Accounting for Manufacturer Rebates. A Study of Original Branded Products in the U.S. October 2016. Available in:https://www.iqvia.com/-/media/iqvia/pdfs/institute-reports/estimate-of-medicare-part-d-costs-after-accounting-for-manufacturer-rebates.pdf