STATE OF MARYLAND

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MARYLAND HEALTH CARE COMMISSION

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January 10, 2014

The Honorable Thomas M. Middleton
Miller Senate Office Building
11 Bladen Street
Annapolis, MD 21401

The Honorable Peter Hammen
241 House Office Building
6 Bladen Street
Annapolis, MD 21401

Dear Senator Middleton and Delegate Hammen:

Attached is the Maryland Health Care Commission (MHCC) report and recommendations on resolving the dispute on the administration of step therapy. This report was requested by the leadership of the General Assembly in a letter to Chairman Craig Tanio at the close of the 2013 legislative session. Mercer's Analysis of Step Therapy is included as an attachment to the report.

MHCC's recommendations are grounded in the work we conducted in the fall and winter of 2013, particularly our own data analysis. Despite challenges and the lack of overall consensus, MHCC believes the following three recommendations are important first steps in reconciling differences:

1. Standardize step therapy grandfathering exemptions to permit patients already successfully managed by a drug or service to continue with that treatment without having to restart step therapy protocols. MHCC recommends that all payors use a one year look back period. Currently, look back periods vary from 130 days to 365 days with exceptions based on the treating physician's documentation.
2. Require all payors to incorporate step therapy approval and override processes in their automated preauthorization applications beginning in July 2015.
3. Require all payors, including Pharmacy Benefit Managers (PBMs), to submit claim information to MHCC. Proposed and emergency regulations to implement this action are now moving through the regulatory process.

These recommendations are summarized in the Executive Summary and are fully described in the Recommendations section of our report. MHCC wishes to emphasize that our recommendations, particularly the implementation of grandfathering, will require further development with the stakeholders to ensure that standards will appropriately cover treatments already successful for chronic and acute conditions.

Separating anecdote from fact in determining the magnitude of provider concerns and the effectiveness of carriers'/PBMs' step therapy protocols was one of the MHCC's biggest challenges. Solid information was surprisingly limited. Practitioner representatives provided only a few patient cases to support their claims and payors offered little research to support their contentions that step therapy ensured that the safest, most frequently effective drugs were used first. MHCC's own review of the research literature revealed that studies on step therapy are sparse.

MHCC conducted its own independent data analysis to measure the scope of step therapy in Maryland. The three largest insurance carriers (Aetna, CareFirst, and UnitedHealthCare) were cooperative and provided list of drugs subject to step therapy. PBMs declined to participate, claiming that the lists of drugs subject to step therapy constituted proprietary information.

Our data analysis showed that step therapy is not an absolute barrier to access. About 18,000 patients insured by the three carriers received drugs that were subject to step therapy, or approximately 1% of the claims analyzed. An additional 56,000 patients received these drugs, but were not subject to step therapy protocols. MHCC could not determine the number of patients that may have been prescribed, but denied a recommended drug, because they had not been treated with the "fail first" drug first.

Greater cooperation is needed among payors and practitioners to achieve all the streamlining each group professes to want. We are confident that more progress can be made. In 2011, payors and practices got off to a slow start in streamlining preauthorization processes. Greater progress was made in 2012. Step therapy could follow that same path over the next year.

Please contact me at 410-764-3565 if you have any questions.

Sincerely,

Ben Steffen
Executive Director

Enclosure

Cc: Secretary Joshua Sharfstein, MD
Chairman Craig Tanio, MD MHCC

Report and Recommendations on Fail-First or Step Therapy

Craig P. Tanio, M.D., Chair

Ben Steffen, Executive Director

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Executive Summary

The Maryland Health Care Commission (MHCC) convened meetings of stakeholders to identify areas for compromise on 'fail first'or step therapy at the request of the leadership in the General Assembly. Four meetings were held during the summer and fall of 2013. Most stakeholders provided information that reflected their respective positions. MHCC retained Mercer, a benefits consulting firm, to assist in gathering information on step therapy practice and to facilitate meetings with the stakeholders. The Mercer report outlines the step therapy process, summarizes perspectives of stakeholders, and documents initiatives in other states that regulate, or have sought to regulate, step therapy.

MHCC staff's work has been constrained by stakeholders' strongly held positions on the value of step therapy and by limited independent data that could be used to support or refute various stakeholders' positions. Most stakeholders had formed strong positions during the debate over the legislation during the 2013 legislative session. MHCC staff found considerable disagreement and confusion among the stakeholders on the scope of step therapy and on carrier/PBM efficiency in administering step therapy protocols. Only a few patient case studies could be documented and some of those were the result of letters sent by patients to MHCC. All stakeholders provided limited substantive information to document their respective positions. Some practitioners confused step therapy with broader preauthorization requirements. Several carriers did not distinguish step therapy from programs that substitute generic therapeutic equivalents for a branded drug. Physicians groups made some of their sharpest allegations about step therapy practices of pharmacy benefits managers (PBMs) but MHCC staff was not able to confirm these allegations due to lack of information.

MHCC staff conducted an independent analysis to assess the scope of step therapy, limiting the analysis to prescription drugs, the benefit where this management tool is most commonly applied.[1] Four leading carriers and the two major PBMs were asked to participate. Three of the four carriers submitted data and one advised MHCC staff that it did not use step therapy. Both PBMs declined to provide claim data, stating that such information was proprietary. The analysis showed that the three remaining carriers subjected about 80 medications to step therapy, with each carrier requiring step therapy on 25 to 30 drugs. Staff's analysis of claim data from the MHCC's Medical Care Data Base (MCDB) showed that about 18,000 patients in fully insured individual, small group, or large group products across the three payors received medication under step therapy protocols. The subset constitutes less than 1 percent of all privately insured patients who received medication in 2012.

MHCC staff could not verify the number of patients who did not receive the recommended medication or medical service because a "fail first" drug was used. Although MHCC maintains claim data in the MCDB, this system does not contain information on denied claims. We were not able to determine the number of patients who were denied a medication because the prescription did not conform to a payor's step therapy protocol.

The lack of information from PBMs limited our ability to generalize results to the overall privately insured market. The absence of information from PBMs is significant as MHCC estimates that approximately 55 percent of prescriptions for the privately insured are processed by

[1] Information from providers indicates only two of the major carriers use step therapy for any medical services, although all payors use other benefit management tools such as preauthorization.

PBMs.[2] Although PBMs and third party administrators are not required to submit claim data to the MCDB, the two leading organizations also refused to identify the medications subject to step therapy, despite our assurances that the list of medications would not be released.

Despite challenges, MHCC staff believes that consensus exists for some possible measures. ***MHCC staff recommends standardizing step therapy grandfathering exemptions to permit patients already well managed by a drug or service to continue with that treatment without having to restart step therapy protocols. Establishing a one year look-back period for patients already effectively controlled by a step therapy service or medication could ensure that effective treatment can continue in most cases.***[3] This look-back or "grandfathering" process is triggered when a patient changes health plans or when a payor changes its formulary. Most payors use a look-back process, but there is little standardization on the duration of the look back. A consistent look-back period would benefit providers that face inconsistent step therapy protocols. A one year look back would mean that a payor would allow a patient to receive the same treatment if records confirm that the service or medication has been used to treat the patient in the preceding year.

A second recommendation builds on the automated preauthorization processes that payors were required to establish as a result of legislation passed in 2012.[4] All major carriers met this requirement; however, practices have been slow in adopting these new electronic protocols. ***MHCC staff recommends requiring payors to expand web-based preauthorization systems to accommodate step therapy transactions, such as approvals and waiver requests, by July 2015.*** These systems can eliminate some of the administrative headaches practices encounter when meeting preauthorization requirements. MHCC staff believes these systems can accommodate step therapy requirements. ***Given slow adoption by practices, this new requirement on payors should be aligned with the requirement that practices use these systems, which was set as of July 2015 in the 2012 legislation.*** Requiring inclusion of step therapy in the automated systems will provide significant benefit to practices and reinforce incentives already put in place by payors.

The MHCC staff also recommends that, consistent with proposed regulations, PBMs and other third party administered submit claim and other information to the MCDB consistent with the requirements on other payors. At its October 2013 meeting, the Commission adopted proposed permanent and emergency replacement regulations (COMAR 10.25.06) that, if adopted as final regulations, will require PBMs to submit the types of data that would have been extremely useful in the MHCC's study of step therapy.

MHCC staff recommends that the General Assembly review approaches that could lead to further standardization of step therapy across all public and private payors. As noted below, step therapy is used by self-insured plans, Medicaid, Medicare Advantage, and Medicare Part D programs. Aside from Medicaid, these other programs are not directly subject to step therapy legislation enacted by the General Assembly. Many payors that participated in the discussions on step therapy these past months also serve self-insured employers, Medicaid, and Medicare. Additional collaboration could produce greater standardization of step therapy programs among payors which would produce the greatest benefit to Maryland patients and providers.

[2] MHCC regulations (COMAR 10.25.06) govern the submission of claim and other data to the MCDB.
[3] In cases in which a payor's first step drug has not been prescribed, the payor should be permitted to request information on what has been previously been prescribed.
[4] Md. Code Ann., Health-Gen. §19-108.2 (2012).

Background

'Fail first' or step therapy is the practice by payors of requiring patients to test use of a safe lower cost drug or service before permitting more expensive drugs or services. Step therapy is an established benefit management tool that is used by commercial carriers, self-insured employers, Medicare Advantage/Part D programs, and Medicaid. Step therapy is one of several management tools that payors use to manage benefits, others include preauthorization (referred to as preauthorization in the Insurance Article) generally and tiered formularies. Preauthorization is the process of obtaining approval from a payor or PBM before a medical or pharmaceutical service can be delivered. Step therapy can be thought of, and is managed under Maryland law, as one type of preauthorization.

These management tools are implemented at different intensities by payors and even by the same payor across different markets. Some medications that are included in a step therapy protocol may be controlled by preauthorization by another payor, and be available only through a specialty drug formulary at a higher patient cost sharing to the patient by a third carrier. As step therapy is one of several possible tools, one possible response to a statutory change could be expansion of existing, or creation of new, management tools.

Step therapy can be used as one tool within various innovative insurance products, such as value based insurance design (VBID). This insurance design has been discussed by the Maryland Health Quality and Cost Council and is being considered by the Department of Budget and Management for the next State employee health plan procurement. The Maryland Health Benefit Exchange has also discussed requiring Qualified Health Plans (QHPs) to include a VBID product among their Exchange offerings.

It is worth noting that the Maryland Insurance Administration (MIA) and the Attorney General's Health Education and Advocacy Unit consider step therapy to be a preauthorization activity that is already regulated under the Insurance Article. MIA provided testimony during the bill hearings in 2013 that a carrier must have a Private Review Agent (PRA) certificate from the MIA or to use a certified PRA to make all preauthorization decisions, including those pertaining to step therapy. MIA further stated that a carrier's denial of coverage for a particular drug or device due to step therapy is a medical necessity denial and is subject to the appeals and grievance process under Title 15, Subtitle 10A.[5]

MHCC has streamlined preauthorization processes using information technology with the collaboration of payors and providers. Maryland law, enacted in 2012, outlines a phased implementation approach for State-regulated payors and PBMs to standardize and automate the process for preauthorizing medical and pharmaceutical services. The law was enacted as a result of recommendations developed by a multi-stakeholder workgroup in 2011 and aims to minimize administrative burdens on providers submitting preauthorization requests. The law established a three-phase implementation approach with various benchmarks and time frames for completion. Phase 1 required payors and PBMs to provide online the list of medical and pharmaceutical services that need a preauthorization and the key criteria for making a determination by October 1, 2012. Phase 2 required payors and PBMs to accept medical and pharmaceutical service preauthorization requests electronically and assign a unique identification number to each

[5] Briefing by Ms. Brenda Wilson, Associate Commissioner Maryland Insurance Administration, on February 27, 2013, "Step Therapy and Fail First Protocols for Prescription Drugs or Devices".

request, for tracking purposes, by March 1, 2013. Phase 3 established time frames for approval and notification of preauthorization requests that were required to be in place by July 1, 2013. Payors and PBMs reported to MHCC on their attainment of the three phases, as well as information on usage, accessibility, and usability of their online preauthorization systems. All payors and PBMs are in compliance with the current preauthorization requirements of the law.

The MHCC retained Mercer to assist in the discussion and study of these issues with the provider and payor communities. MHCC sought input from Mercer as they could bring together a team of clinical and benefit design experts that would be knowledgeable about the implementation of step therapy in a variety of markets. The Mercer team of consultants participated in the meetings with the individual stakeholders and the final meeting with all stakeholders. Mercer's report, *Step Therapy Analysis*, which is attached, provides a broad background on step therapy, reviews step therapy program legislation in other states, describes the positions of the various stakeholders on step therapy, and outlines potential areas for compromise. The following analysis builds on information in the Mercer Report and provides empirical data on the implementation of step therapy by the leading carriers in the State.

MHCC's Analysis of Current Step Therapy Protocols

To augment the Mercer Report with evidence from the Maryland market, MHCC asked the major carriers (Aetna, CareFirst, United HealthCare, and Kaiser) and the largest pharmacy benefit management companies (CareMark and Express Scripts) to provide information on their step therapy programs with the understanding that the Commission would not identify any payor. Three of the four carriers agreed to provide lists, a fourth responded that it did not use step therapy. Both PBMs declined, arguing that the drugs subject to step therapy were proprietary and confidential to their organizations. Commission staff decided to launch a more limited analysis using the lists provided by the three carriers.

Carriers reported that a small number of drugs are subject to step therapy protocols in Maryland. Actual numbers varied from 25 to 30, depending on the payor.[6] Table 1 presents the categories of drugs that may be subject to Step Therapy. For illustrative purposes only, certain drugs subject to step therapy are listed by the major drug categories[7]. A combined list of step therapy medications provided by the three carriers is included as Attachment 1.

[6] The actual drug lists submitted by carriers were organized by National Drug Codes and were therefore larger because many medications are manufactured by different producers in a variety of strengths and packet sizes. It is common for one medication to be associated with many NDCs.

[7] MHCC staff found no instances where a payor required all medications in a treatment category to be prescribed under step therapy protocols.

Table 1 – Conditions that May be Subject to Step Therapy Protocols (analysis limited to 3 carriers)

Condition	No. of Drugs Identified	Illustrative Drugs*
Asthma	1	Maxair
Certain Bacterial Infections	1	Solodyn
Crohn's Disease	1	Cimzia
Diabetes	2	Lantus,Novolin
Diseases Of The Pancreas & Post-Gastrointestinal Bypass Surgery	3	Pertzye,Ultresa
Epilepsy	6	Oxtellar XR, Depakote ER, Stavzor
Gastroesophageal Reflux Disease (Gerd), Ulcers	3	Aciphex,Nexium
Growth Hormone Deficiency, Intestinal Disorder, Hiv-Related Weight Loss	6	Genotropin, Humatrope
Hepatitis C	2	**Pegintron**
High Cholesterol	1	Lipitor
Hypertension	11	Atacand/HCT,Avalide,Edarbyclor, Teveten
Impotence	4	Cialis, Levitra
Infertility	2	Bravelle
Insomnia	8	Ambien, Edluar,Rozerem
Kidney Disease	2	Aranesp,Renagel
Low Testosterone	3	Axiron,Striant
Migraine/Epilepsy	1	Topomax
Multiple Sclerosis[8]	7	Acthar Hp, Avonex, **Betaseron, Extavia,Gilenya**,Tecfidera
Osteoporosis	2	Boniva
Overactive Bladder	1	Oxytrol
Psoriasis	1	Stelara
Rheumatoid Arthritis	6	Actemra,Humira, Kineret, **Xeljanz**
Type 2 Diabetes	3	Actoplus MET, Bydureon

Note: Drugs in bold type are included in two carriers' step therapy programs.

* See Attachment 1 for all drugs that the three carriers subjected to step therapy in 2012.

Based on a review of drugs supplied by carriers, MHCC staff found approaches to managing high cost drugs varied by payor. In general, a drug is subject to step therapy due to cost and other factors because a carrier determines an alternative drug is a more cost effective alternative. This formula appeared to be applied by each carrier, but the drugs, sometimes even the drug classes, that are subject to step therapy vary by carrier. For example, one carrier used step therapy to direct patients to a specific growth hormone treatment as the first step. The other

[8] In the last several years, pharmaceutical companies have introduced new disease-modifying agents for the treatment of relapse remitting MS patients, including Aubagio, Avonex, Betaseron, Copaxone, Extavia, Gilenya Novantrone, Rebif, Tecfidera, and Tysabri. No carrier applied step therapy to every drug in this narrow class of treatments.

two carriers did not apply step therapy to any medication in this drug class.[9] All three carriers used step therapy to manage the drugs prescribed to treat multiple sclerosis (MS). MHCC staff found that all MS drugs subject to step therapy could be considered higher cost specialty drugs. However, each carrier flagged different MS drugs as subject to step therapy.

Managing approaches for higher utilization drug categories, such as sleep medication, tended to be even more varied. One carrier placed step therapy controls on several frequently prescribed sleep medications, a second carrier had a more limited sequence of drugs, and a third carrier had no step therapy controls at all. A similar pattern was observed with treatments for impotence. One carrier applied step therapy to two of the three most commonly prescribed drugs, a second carrier applied step therapy to one of the drugs, and the third carrier appeared to allow prescribers to order any of the three most commonly prescribed drugs to treat impotence. Of the nearly 80 medications on the combined list, no medication was subject to step therapy by all 3 carriers. Only five drugs, (Betaseron,Extavia,Gilenya, Pegintron, Xeljanz,) were on the step therapy lists of 2 carriers. All five of these drugs cost more than $500 per prescription.[10] The lack of consistency in the drugs that are subject to step therapy means that practices must confirm the drugs that can be used based on the insurance coverage of the patient.

The varied approaches to managing certain classes of drugs are confusing to practices. Some services and medications may be subject to step therapy by one payor, governed by preauthorization by another, and be part of the preferred branded formulary with no controls by a third payor. MHCC staff believes that even greater variation would be observed if additional carriers and PBMs had identified drugs subject to step therapy.

MHCC staff's review of drugs confirmed patients' and providers' claim that the drugs subject to step therapy are inconsistent across carriers. This finding needs to be qualified because the number of drugs is quite small and step therapy is but one form of benefit management. Some payors impose preauthorization requirements instead of step therapy. In some instances, the same payor uses different rules for different markets. MHCC staff found some medications that were subject to step therapy in the Maryland privately insured market were listed as being subject to preauthorization in that payor's Medicare Part D program. More worrisome, some payors may drop a drug completely from its formulary, forcing a patient to pay out-of-pocket for the full cost of the medication.

Some patients and providers claim that step therapy protocols prevent patients from ever receiving the drug that the prescriber judges as most appropriate. The MHCC staff checked drugs flagged as governed by step therapy against the Medical Care Data Base prescription drug claims for 2013. For this analysis, MHCC staff limited the sample to individuals who were fully insured in the individual, small group, large group markets, and the Maryland Health Insurance Plan (MHIP). The sample was further limited to patients who had at least one prescription in 2012, yielding a sample of approximately 1.1 million patients. Table 2 summarizes the results of this analysis.

[9] One carrier indicated it controlled growth hormones through preauthorization.

[10] Three (Extavia, Beteseron, and Gilenya) of the five drugs are MS disease modifying with annual costs of between $35,000 and $60,000. Petgintron (used in the treatment of chronic hepatitis C) costs about $9,000 per year and Xeljanz (used to treat rheumatoid arthritis) costs approximately $25,000 per year.

The number of patients directly affected by step therapy is quite small. Overall 73,359 scripts were filled for medications subject to step therapy for 18,073 patients.[11] These figures represent less than 1 percent of all prescriptions and less than 2 percent of all patients. Another 55,807 patients used drugs that were subject to step therapy by other payors, but were not themselves affected because their payor did not impose a step therapy requirement on that drug. Roughly 2 percent of all prescriptions fell in this category.

Significantly more people are being treated by drugs subject to step therapy outside of the protocol than under the protocol. This estimate needs to be interpreted cautiously because most of the drugs identified as requiring "fail first" treatment are flagged by only one carrier. The number of patients receiving the drug outside of the protocol will likely be higher as only one carrier uses the step therapy protocol for any particular drug. This will certainly be true if one of the carriers not using step therapy protocol for a particular drug is CareFirst, the largest payor in the Maryland market.

Table 2: Number of Scripts Written and Patients Treated with Drugs Subject to Step Therapy

	Scripts		Patients	
	Number	Percent	Number	Percent
Drug Administered Under Step Therapy*	73,359	0.6%	18,073	1.7%
Drug Administered without Step Therapy**	229,139	1.7%	55,887	5.1%
Overall Total receiving Step drugs (All patients receiving a step drug)***	302,498	2.3%	73,960	6.8%
All Fully Insured Patients (Patients receiving any drug)	13,213,033	100.0%	1,088,393	100.0%

* Patients that received prescriber recommended drug under step therapy and were insured by one of the three largest carriers.
** Patients that received a drug governed by step therapy, but were not themselves subject to step therapy rules and were insured by the three largest carriers or others.
*** Patients may be double counted because they could be receiving both stepped and non-stepped medications.

These results highlight several additional conclusions. Drugs assigned to step therapy vary across carriers. Prescribers face considerable uncertainty in identifying which medications are stepped for any one prescriber. The variation among the drugs subject to step therapy lists presents challenges to patients already well-managed by a medication. When a patient changes payor, the patient's care could be disrupted because a prescribed medication could potentially be denied because the "fail first" drug may not been previously prescribed. Even in instances when

[11] The Medical Care Data Base does not contain denied claims, so it is not possible for staff to estimate the number of patients who were prescribed a step therapy drug and were denied because a "fail first" drug needed to be prescribed first. It is not possible to determine through this limited analysis how many patients would have been treated had step therapy not been applied.

a carrier can "look back" over a patient's claim history, failure to prescribe the "fail first" drug could generate a denial.

Recommendations

MHCC staff recommends standardizing step therapy grandfathering exemptions to permit patients already well managed by a drug or service to continue with that treatment without having to restart step therapy protocols. Step therapy should not impose additional requirements on patients already under successful treatment unless patient and physician conclude it is in the best interest of the patient. The "grandfathering" exemption should apply to a patient with either chronic or acute conditions. As long as a medication is in the payor's formulary, the "grandfathering" exemption should apply regardless of whether the patient has previously failed a payor's step 1 treatment or the patient has changed payors.[12] For chronic conditions in which medications are prescribed on a continuing basis, determining whether a medication has been established as effective will require a look back into the claim history or the medical records held by the prescriber or by another physician's practice. MHCC staff recommends that all payors adopt a one-year look-back period for acute therapies that are not continuously administered. Payors should accept claims histories supplied by the patient, a predecessor payor, or the medical records maintained by a practice. A payor should be responsible for maintaining at least one year of claim data to support the look back. A patient or the prescribing physician should have the burden of gathering supporting evidence held in the patient's medical record.

MHCC staff recommends requiring payors to expand web-based preauthorization systems to accommodate step therapy transactions, such as approvals and waiver requests, by July 2015 when payers can require use. Mandating that payors support step therapy processing by July 2015 will further expand the use of these systems. The existing preauthorization automated process could be used for managing step therapy approval and waiver transactions. Payors are already required to implement automated systems for fulfilling prior authorization requirements. All major payors and PBMs met that requirement in July 2013 and these systems can be modified to accommodate step therapy protocols. Although the rollout is in its early stages, adoption of these systems by practices has been discouragingly slow. MHCC has previously reported that, among payors and PBMs that had electronic preauthorization systems available in 2012 and the first half of 2013, only about 18 percent of medical service preauthorization requests were submitted via these systems. In addition, only one percent of pharmaceutical service preauthorization requests were submitted electronically in the first 6 month reporting period.[13] As shown in Table 3, payors reported little improvement between 2012 and 2013, when most payors had their new preauthorization systems in operation. Payors and practice organizations need to invest more resources in promoting these systems. Layering step therapy into the system promotes adoption and thereby benefits all stakeholders. As previously noted, the MIA considers step therapy to be one type of preauthorization. Payors who communicated with MHCC staff emphasized that step therapy was part of the broader preauthorization benefit management tool. Requiring web-based preauthorization approval systems to support step therapy is consistent with this perspective***. To increase the pace of adoption, MedChi,***

[12] If the 'fail first' drug has not been prescribed, that payor should have an option to require the prescriber to document what has been previously tested before agreeing to waive step therapy.

[13] Maryland Health Care Commission, ***State-Regulated Payor & Pharmacy Benefit Manager Preauthorization Benchmark Attainment***, October 2013, available at http://mhcc.dhmh.maryland.gov/hit/hie/Documents/preauth_oct_2013.pdf

physician specialty societies, and payors should launch coordinated outreach efforts to broaden use of these systems by physician practices.

Some preauthorization systems can already accommodate step therapy requirements without any modifications. Several MHCC Commissioners and staff received a demonstration of CareFirst and Caremark's preauthorization systems on December 10, 2013. MHCC staff confirmed that these systems could streamline step therapy processing for physicians if practices were willing to use the automated tools. One payor demonstrated the preauthorization process for a drug included in that payor's step therapy program. Use of electronic preauthorization systems remained consistently low from calendar year 2012 through the 2013 reporting period.

Table 3 -- Estimated Volume of Medical and Pharmaceutical Service Preauthorization Requests in Maryland[14]

	Preauthorization Requests 2012	*Claims 2012*	*% of Preauthorization Requests Submitted Electronically 2012 (%)*	*% of Preauthorization Requests Submitted Electronically January-June 2013 (%)*
Payor				
Aetna, Inc. Pharmaceutical Services[1]	114,141	1,440,800	< 1	< 1
Aetna, Inc. Specialty Pharmaceutical Services[1]	♦	86,000	< 2	< 5
CareFirst BlueCross BlueShield[2]	23,500	11,235,795	*	< 1
Cigna Health and Life Insurance Company/ Connecticut General Life Insurance Company Pharmaceutical Services[3]	♦	1,036,719	♦	
Coventry Health Care of Delaware, Inc.[4]	2,400	380,000	*	< 1
PBM				
Catamaran[5]	128,481	3,038,088	*	■
CVS Caremark[6]	**180,000**	**25,000,000**	**< 1**	**< 1**
Envision Pharmaceutical Services, Inc.[7]	2,450	213,390	*	0
Express Scripts, Inc.[8]	**112,241**	**17,500,715**	**< 1**	**< 1**
Pharmaceutical Technologies, Inc.[9]	**		*	0
UnitedHealthcare OptumRx[3]	**			< 1

Notes
1 = Fully-insured, self-insured, commercial, Medicare (excludes Medicaid)
2 = Includes Maryland, Virginia, and Washington D.C.; fully-insured, self-insured, Medicare Part D
3 = Fully-insured
4 = Fully-insured, self-insured
5 = Fully-insured, self-insured, Medicare
6 = Fully-insured, self-insured, commercial, Medicare, Medicaid
7 = Self-insured and Medicare Part D
8 = Fully-insured, employer, Medicaid, Medicare
9 = Fully-insured, self-insured, commercial, Medicare, and workmen's compensation
* = Online system to accept preauthorization requests was not available in 2012
** = Payor/PBM did not operate in Maryland in 2011 and/or 2012
♦= Data not provided

[14] Ibid., p 5

Table 3 -- Estimated Volume of Medical and Pharmaceutical Service Preauthorization Requests in Maryland[14]				
	Preauthorization Requests 2012	***Claims 2012***	***% of Preauthorization Requests Submitted Electronically 2012 (%)***	***% of Preauthorization Requests Submitted Electronically January-June 2013 (%)***
●= Reported as confidential ■ = Payor/PBM has a waiver for an extension of time for this requirement				

Other reforms should be considered after grandfathering standards have been accepted and fuller adoption of automated preauthorization by practices has occurred. Payors and providers differ on other aspects of step therapy. The Mercer Report examined limitations on the duration of a step 1 drug/service to a single 30-day trial. Setting standards for when peer consultations could be required, and streamlining an appeal process would be beneficial to patients and providers. The report suggested that a 30-day limit might be an area for compromise.[15] A single threshold, while operationally simple, may be too rigid in practice for both payors and providers. Payors referenced several drugs classes, including typical and atypical psychotropics that sometimes require longer than 30 days to judge therapeutic effectiveness. Conversely, several providers also indicated that 30 days could be too long a period for certain drugs. For example, many hypertension treatments can be judged as effective in a much shorter time period. Rather than setting a defined floor, it may be more productive to determine how a streamlined opt-out protocol could be implemented within the framework of the electronic preauthorization tools recently established by payors.

Peer consults and appeal processes are another area where payors contend well-established internal procedures already exist and where providers argue greater standardization and further streamlining is needed. Several payors also contended that appeal processes are already defined in the Insurance Article and in MIA regulations. In these payors' view, carving out special rules for a particular benefit management tool compounds payors' challenges in serving the Maryland market. For providers, existing payor-specific procedures and the MIA requirements were not adequate to meet the need of prescribers to obtain timely waivers from step therapy rules.

Lastly, MHCC recommends that, assuming that proposed regulations become effective, MHCC staff use claim and other information that will be submitted by PBMs and other third party administrators to the MCDB (just as all carriers already submit claims) to evaluate the impact of step therapy protocols. In October 2013, MHCC adopted a replacement COMAR 10.25.06 as emergency and proposed regulations, which contain requirements that PBMs submit claim and other types of information that would be useful for the analysis conducted in this report. PBMs already submit such data in more than a dozen states. Staff notes that the simple collection of data from PBMs and third party administrators is not prohibited by ERISA (although certain parts of insurance regulation that act immediately and exclusively on ERISA plans would be prohibited). The State of Maryland and the MHCC have a legitimate interest in obtaining the information needed in order to fulfill its duty to regulate and assure the delivery of quality health care at an affordable cost in the State, an issue that is historically a matter of state concern. The collection of claims data does not target PBM or ERISA plans generally and furthers the important

[15] Mercer, ***Step Therapy Analysis***, December 10, 2013.

State interest of improving the health care provided to Maryland residents. Our analysis in this report would have been significantly enhanced, if PBMs had provided requested information on step therapy.

Other Considerations

Several payor representatives reminded MHCC staff that Maryland's ability to regulate step therapy is limited because self-insured employers, Medicare Advantage and Part D Drug Plans, and potentially the Medicaid pharmacy program would be exempt from any State reform. MHCC staff estimates that approximately 30 percent of the publicly and privately insured population would be directly affected by the step therapy proposal that was debated in 2013.[16]

Broad-based voluntary initiatives that engage non-regulated entities could benefit more patients and practices than changes limited to State-regulated entities. Payors may unilaterally align their step therapy protocols across all of the markets they serve so that practices face consistent step therapy rules. The large private carriers, including Aetna and United HealthCare, offer Medicare Part D programs, as do CareMark and Express Scripts. Kaiser and Aetna market Medicare Advantage plans that include embedded drug benefits. MHCC staff concludes that broader initiatives, in conjunction with greater standardization, could be useful to providers. MHCC staff could assist in this effort.

Many provider organizations have recognized the need for physicians, patients, and other health care stakeholders to think and talk about medical care that may be unnecessary, or in some cases should be provided only after other safe drugs, procedures, or services have been attempted. One effort of particular note is the ***Choosing Wisely***© initiative launched by the American Board of Internal Medicine. As of December 2013, over 50 national medical societies have created lists of "Things Physicians and Patients Should Question" that contain evidence-based recommendations to discuss in making informed decisions about the most appropriate care based on a patient's individual situation. Benefit management by plans and cost reduction efforts by medical societies are not aligned at present, although overall objectives may not differ as much as some in the payor and provider community would contend. The fact that stakeholders are independently working on identifying cost effective "first-step" services suggests that further progress is possible. Increased focus on the management of the total costs of care and the growing acceptance of incentive-based payments that relate to outcomes may be a more effective way to manage health care costs. In a survey conducted by the Commonwealth Fund in 2009, health care opinion leaders ranked prior authorization and limiting patient access to expensive or high-volume health care as one of the less effective tools for controlling health care costs.[17]

MHCC staff concludes that it is important to remember that step therapy is but one benefit management tool among several that payors use to control utilization. Attempts to

[16] A number of large public employers selectively adopt state mandates, so it is often difficult to precisely report the percent of the population that could affected. A decision to cover a state mandate is made at a self-insured employer's discretion. The 30 percent estimated should be viewed as the lower bound of coverage for a limit on step therapy.

[17] ***Health Care Opinion Leaders Views on Slowing the Growth of Health Care Costs,*** Commission on a High Performance Health System, April 2009 accessed at ***http://www.commonwealthfund.org/Surveys/2009/April/Health-Care-Opinion-Leaders-Survey-on-Slowing-the-Growth-of-Health-Care-Costs.aspx***

eliminate use of step therapy could trigger more aggressive use of other tools. Particularly worrisome is the increased use of tiered formularies in which the higher tiers consisting of specialty drugs and biologics have the highest cost sharing requirements. MHCC found that 50 percent cost sharing in the specialty drug tier was not uncommon in products offered in the individual market for 2014. Higher cost sharing may be less beneficial to patients than step therapy. Preauthorization denials are appealable, but a requirement that a patient pay more for a drug is not considered a medical necessity decision because benefits are not denied, but are covered with higher cost sharing.

Some payors may attempt to eliminate some high costs drugs from formularies if step therapy is curtailed. In late 2013, two national PBMs, CareMark and Express Scripts, announced they would eliminate a number of branded and high cost drugs from their formularies. In some instances, the branded agents that were dropped from the formularies have generic equivalents that will continue to be available. Other dropped drugs were high cost specialty drugs for which no generic therapeutic equivalents are available.[18] These actions are not directly related to the debate on step therapy in Maryland, although it is also worth noting that some of the drugs dropped from the formularies are drugs that one or more of the carriers subjects to step therapy. Actions by these PBMs only demonstrate that other approaches to managing high cost and branded drugs are available. These methods could have more serious consequences on patients than step therapy requirements. Copies of the CareMark and Express Script announcements for 2014 are included as Attachment 2.

The impact of the Affordable Care Act (ACA) may have other unintended consequences on access to certain classes of drugs. The ACA requires that issuers (carriers) include reasonable numbers of drugs in all treatment classes for products sold in the individual and small group markets beginning January 1, 2014.[19] These requirements largely focus on the number of drugs that must be offered in each United States Pharmacopeia (USP) drug class.

MHCC staff recognizes the challenges presented to patients and providers by step therapy requirements. Payors often make compelling cost or quality arguments when describing their step therapy methodology. Yet too much variation exists. Although our analysis shows that only a small number of drugs are subject to this management tool, the number of patients affected is meaningful. MHCC staff will work with payors and practices to further define standards for grandfathering existing patients' use of services or medications and to align payors' preauthorization systems for use in step therapy review. If progress can be made in these areas, compromises on all aspects of step therapy may be easier to achieve.

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[18] Drugs covered by step therapy by one of the major carriers that were dropped in 2013 or 2014 by CareMark included Atacand, Atacand HCT, Edarbi, Edarbyclor, Genotropin, Intermezzo, Levitra, Maxair, Nutropin, Omnitrope, Oxytrol, Rozerem, Testim, Teveten, Teveten/HCT, Tev-Tropinand. Drugs covered by one of the three major carriers that were dropped in 2014 by Express Scripts included Betaseron, Bravelle, Edarbi, Edarbyclor, Levitra, Maxair, Nutropin/Nutropin, Omnitrope, PegIntron, Simponi, Testim, Teveten/Teveten HCT, Tev-Tropin and Xeljanz.

[19] The final federal rule on the development of formularies requires that a plan must cover "at least the greater of": one drug in every category and USP class or the same number of drugs in each category and class as the benchmark plan. See page 46 in ***Patient Protection and Affordable Care Act; Standards Related to Essential Health Benefits, Actuarial Value, and Accreditation*** at https://s3.amazonaws.com/public-inspection.federalregister.gov/2013-04084.pdf

Attachment 1: Medications Subject To Step Therapy by at Least 1 Major Carrier

High Cost	Common name	Commonly Used to Treat	No. of Carriers using Step Therapy
	Aciphex	Gastroesophageal Reflux Disease (GERD), Ulcers	1
X	Actemra	Rheumatoid Arthritis	1
	Acthar Hp	Multiple Sclerosis	1
	Actoplus Met	Type 2 Diabetes	1
	Ambien, Ambien CR	Insomnia	1
X	Aranesp	Kidney Disease	1
	Atacand/HCT	Hypertension	1
X	Aubagio	Multiple Sclerosis	1
	Avalide	Hypertension	1
	Avapro	Hypertension	1
X	Avonex, Avonex Adm Pack, Aonex Pen	Multiple Sclerosis	1
	Axiron	Low Testosterone	1
	Benicar/Hct	Hypertension	1
X	Betaseron	Multiple Sclerosis	2
	Boniva	Osteoporosis	1
X	Bravelle	Infertility	1
	Bydureon	Type 2 Diabetes	1
	Cialis	Impotence	1
X	Cimzia	Crohn's Disease, Rheumatoid Arthritis	1
	Cozaar	Hypertension	1
	Depakote, ER	Epilepsy	1
	Edarbi	Hypertension	1
	Edarbyclor	Hypertension	1
	Edluar	Insomnia	1
X	Extavia	Multiple Sclerosis	2
X	Follistim	Infertility	1
	Fosamax Plus D	Osteoporosis	1
	Genotropin	Growth Hormone Deficiency, Intestinal Disorder, HIV-Related Weight Loss Or Wasting	1
X	Gilenya	Multiple Sclerosis	2
X	Humatrope	Growth Hormone Deficiency, Intestinal Disorder, HIV-Related Weight Loss Or Wasting	1
X	Humira	Rheumatoid Arthritis	1
	Hyzaar	Hypertension	1
	Intermezzo	Insomnia	1
	Keppra,Keppra CR	Epilepsy	1
X	Kineret	Rheumatoid Arthritis	1

Attachment 1: Medications Subject To Step Therapy by at Least 1 Major Carrier

High Cost	Common name	Commonly Used to Treat	No. of Carriers using Step Therapy
	Lamictal (blue, Green,Orange)	Epilepsy/Bipolar	1
	Lamotrigine	Epilepsy/Bipolar	1
	Lantus,Lantus Solostar	Diabetes	1
	Levitra	Impotence	1
	Lipitor	High Cholesterol	1
	Lunesta	Insomnia	1
X	Maxair	Asthma	1
	Nexium	Gastroesophageal Reflux Disease (Gerd), Ulcers	1
	Novolin	Diabetes	1
	Nutropin	Growth Hormone Deficiency, Intestinal Disorder, Hiv-Related Weight Loss Or Wasting	1
X	Omnitrope	Growth Hormone Deficiency, Intestinal Disorder, Hiv-Related Weight Loss Or Wasting	1
X	Orencia	Rheumatoid Arthritis	1
	Oxtellar XR	Epilepsy	1
	Oxytrol	Overactive Bladder	1
X	Pegintron	Hepatitis C	2
	Pegintron Redipen	Hepatitis C	1
	Pertzye	Diseases Of The Pancreas And Post-Gastrointestinal Bypass Surgery	1
	Relion	Type 2 Diabetes	1
	Renagel	Kidney Disease	1
	Rozerem	Insomnia	1
X	Saizen	Growth Hormone Deficiency, Intestinal Disorder, Hiv-Related Weight Loss Or Wasting	1
X	Simponi	Rheumatoid Arthritis	1
	Solodyn	Tetracycline Antibiotic – Used To Treat Certain Bacterial Infections	1
	Sonata	Insomnia	1
	Stavzor	Epilepsy/Bipolar	1
	Staxyn	Impotence	1
X	Stelara	Psoriasis	1
	Striant	Low Testosterone	1
X	Tecfidera	Multiple Sclerosis	1
	Testim	Low Testosterone	1
	Teveten	Hypertension	1
	Teveten/HCT	Hypertension	1

Attachment 1: Medications Subject To Step Therapy by at Least 1 Major Carrier

High Cost	Common name	Commonly Used to Treat	No. of Carriers using Step Therapy
	Tev-Tropin	Growth Hormone Deficiency, Intestinal Disorder, Hiv-Related Weight Loss Or Wasting	1
	Topamax	Migraine/Epilepsy	1
	Twynsta	Hypertension	1
	Ultresa	Diseases Of The Pancreas And Post-Gastrointestinal Bypass Surgery	1
	Viagra	Impotence	1
	Viokace	Diseases Of The Pancreas And Post-Gastrointestinal Bypass Surgery	1
X	Xeljanz	Rheumatoid Arthritis	2
	Zegerid	Gastroesophageal Reflux Disease (Gerd), Ulcers	1
	Zolpidem ER	Insomnia	1
	Zolpimist	Insomnia	1

Note: High cost is defined as having a total cost of $500 or greater for a typical prescription. Some of the drugs listed as high cost have a total cost of more than $5,000 per typical prescription.

Attachment 2 – PBMs' Announcements Of Medications To Be Dropped From Formularies In 2014

January 2014

Formulary Drug Removals

Below is a list of medicines by drug class that have been removed from your plan's formulary. This list is effective January 1, 2014. If you continue using one of the drugs listed below and identified as a Formulary Drug Removal after this date, you may be required to pay the full cost.

If you are currently using one of the formulary drug removals, ask your doctor to choose one of the generic or brand formulary consideration options listed below.

Bolded products represent formulary drug removals that are new for the 2014 plan year.

Category * Drug Class	Formulary Drug Removals	Formulary Considerations
Allergies * Nasal Steroids / Combinations	BECONASE AQ OMNARIS QNASL RHINOCORT AQUA VERAMYST **ZETONNA**	*flunisolide spray, fluticasone spray, triamcinolone spray,* NASONEX
	DYMISTA	*flunisolide spray, fluticasone spray, triamcinolone spray, or* NASONEX **WITH** *azelastine or* ASTEPRO
Allergies * Ophthalmic	**LASTACAFT**	*azelastine, cromolyn sodium,* ALREX, PATADAY
Asthma * Beta Agonists, Short-Acting	MAXAIR **VENTOLIN HFA** XOPENEX HFA	PROAIR HFA, PROVENTIL HFA
Asthma * Steroid Inhalants	**ALVESCO**	ASMANEX, FLOVENT, PULMICORT FLEXHALER, QVAR
Asthma * *or Chronic Obstructive Pulmonary Disease (COPD)* * Steroid / Beta Agonist Combinations	**BREO ELLIPTA**	ADVAIR, DULERA, SYMBICORT
Chronic Obstructive Pulmonary Disease (COPD) * Anticholinergics	**TUDORZA PRESSAIR**	SPIRIVA
Depression * Antidepressants	OLEPTRO	*trazodone*
Diabetes * Biguanides	GLUMETZA RIOMET	*metformin, metformin ext-rel*
Diabetes * Dipeptidyl Peptidase-4 (DPP-4) Inhibitors	**NESINA** ONGLYZA	JANUVIA, TRADJENTA
Diabetes * Dipeptidyl Peptidase-4 (DPP-4) Inhibitor Combinations	**KAZANO** KOMBIGLYZE XR **OSENI**	JANUMET, JANUMET XR, JENTADUETO

CVS CAREMARK

Category * Drug Class	Formulary Drug Removals	Formulary Considerations
Diabetes * Insulins	HUMALOG	APIDRA, NOVOLOG
	HUMALOG MIX 50/50	NOVOLOG MIX 70/30
	HUMALOG MIX 75/25	NOVOLOG MIX 70/30
	HUMULIN 70/30	NOVOLIN 70/30
	HUMULIN N	NOVOLIN N
	HUMULIN R	NOVOLIN R
	NOTE: *Humulin U-500 concentrate will not be subject to removal and will continue to be covered.*	
Diabetes * Supplies [1]	**BREEZE 2 STRIPS AND KITS** **CONTOUR STRIPS AND KITS** **CONTOUR NEXT STRIPS AND KITS** FREESTYLE STRIPS AND KITS [2]	ACCU-CHEK STRIPS AND KITS [1], ONETOUCH STRIPS AND KITS [1]
Erectile Dysfunction * Phosphodiesterase Inhibitors	LEVITRA	CIALIS, VIAGRA
Glaucoma * Prostaglandin Analogs	LUMIGAN	*latanoprost*, TRAVATAN Z, ZIOPTAN
Growth Hormones *	GENOTROPIN NUTROPIN / NUTROPIN AQ OMNITROPE SAIZEN TEV-TROPIN	HUMATROPE, NORDITROPIN
High Blood Pressure * Angiotensin II Receptor Antagonists	EDARBI	*candesartan, eprosartan, irbesartan, losartan*, BENICAR, DIOVAN, MICARDIS
High Blood Pressure * Angiotensin II Receptor Antagonist / Diuretic Combinations	EDARBYCLOR TEVETEN HCT	*candesartan-hydrochlorothiazide, irbesartan-hydrochlorothiazide, losartan-hydrochlorothiazide, valsartan-hydrochlorothiazide*, BENICAR HCT, MICARDIS HCT
High Cholesterol * HMG Co-A Reductase Inhibitors (HMGs or Statins)	ALTOPREV **LESCOL XL** LIVALO	*atorvastatin, fluvastatin, lovastatin, pravastatin, simvastatin*, CRESTOR
High Cholesterol * HMG Co-A Reductase Inhibitor Combinations	ADVICOR	*atorvastatin, fluvastatin, lovastatin, pravastatin, simvastatin*, SIMCOR
	LIPTRUZET	*atorvastatin, fluvastatin, lovastatin, pravastatin, simvastatin*, VYTORIN
Inflammatory Bowel Disease (IBD), Ulcerative Colitis * Aminosalicylates	**ASACOL HD** **DELZICOL**	*balsalazide, sulfasalazine, sulfasalazine delayed-rel*, APRISO, LIALDA, PENTASA
Opioid Dependence Agents *	**SUBOXONE FILM**	*buprenorphine/naloxone sublingual tablets*
Overactive Bladder / Incontinence * Urinary Antispasmodics	DETROL LA OXYTROL [2] TOVIAZ	*oxybutynin ext-rel, tolterodine, trospium, trospium ext-rel*, GELNIQUE, VESICARE

Category * Drug Class	Formulary Drug Removals	Formulary Considerations
Pain and Inflammation * Nonsteroidal Anti-inflammatory Drugs (NSAIDs)	FLECTOR	*diclofenac, meloxicam, naproxen*
Pain and Inflammation * Corticosteroids	RAYOS	*dexamethasone, methylprednisolone, prednisone*
Prostate Condition * Benign Prostatic Hyperplasia Agents / Combinations	JALYN	*finasteride* or AVODART **WITH** *alfuzosin ext-rel, doxazosin, tamsulosin, terazosin* or RAPAFLO
Sleep * Hypnotics, Non-benzodiazepines	INTERMEZZO ROZEREM	*zolpidem, zolpidem ext-rel*
Testosterone Replacement * Androgens	ANDROGEL TESTIM	ANDRODERM, AXIRON, FORTESTA
Transplant * Immunosuppressants, Calcineurin Inhibitors	Hecoria	*tacrolimus*

The listed formulary considerations are subject to change.

List of Formulary Drug Removals - *Carryover from 2013*

ADVICOR	HUMALOG MIX 50/50	ONGLYZA
ALTOPREV	HUMALOG MIX 75/25	OXYTROL [2]
ANDROGEL	HUMULIN 70/30	QNASL
ARTHROTEC	HUMULIN N	RHINOCORT AQUA
ATACAND	HUMULIN R	RIOMET
ATACAND HCT	INTERMEZZO	ROZEREM
BECONASE AQ	JALYN	SAIZEN
DETROL LA	KOMBIGLYZE XR	SANCTURA XR
EDARBI	LEVITRA	TESTIM
EDARBYCLOR	LIVALO	TEVETEN
FLECTOR	LUMIGAN	TEVETEN HCT
FORTAMET	MAXAIR	TEV-TROPIN
FREESTYLE STRIPS AND KITS [2]	NUTROPIN / NUTROPIN AQ	TOVIAZ
GENOTROPIN	OLEPTRO	VERAMYST
GLUMETZA	OLUX-E	XOPENEX HFA
Hecoria	OMNARIS	
HUMALOG	OMNITROPE	

List of Formulary Drug Removals - *New for 2014*

ACTOS	DYMISTA	PREVACID
ALVESCO	KAZANO	PROTONIX
ASACOL HD	LASTACAFT	RAYOS
BREEZE 2 STRIPS AND KITS	LESCOL XL	SUBOXONE FILM
BREO ELLIPTA	LIPITOR	TRICOR
CONTOUR STRIPS AND KITS	LIPTRUZET	TUDORZA PRESSAIR
CONTOUR NEXT STRIPS AND KITS	NESINA	VALTREX
DELZICOL	OSENI	VENTOLIN HFA
DIOVAN HCT	PLAVIX	ZETONNA

The following drugs have generic availability. The brand drugs listed below have been removed from your plan's formulary. Ask your doctor to choose the generic equivalent of these brand drugs.

Branded Agents Removed from Formulary that Have Generic Equivalents Available [3]		
ACTOS	FORTAMET	PROTONIX
ARTHROTEC	LIPITOR	SANCTURA XR
ATACAND	OLUX-E	TEVETEN
ATACAND HCT	PLAVIX	TRICOR
DIOVAN HCT	PREVACID	VALTREX

This list represents brand products in CAPS, branded generics in upper- and lowercase, and generic products in lowercase italics. This is not an all-inclusive list of available drug alternative considerations. Log in to www.caremark.com to check coverage and copay information for a specific drug. Discuss this information with your doctor or health care provider. This information is not a substitute for medical advice or treatment. Talk to your doctor or health care provider about this information and any health-related questions you have. CVS Caremark assumes no liability whatsoever for the information provided or for any diagnosis or treatment made as a result of this information. This list is subject to change. There may be additional plan restrictions. Please consult your plan for further information.

Subject to applicable state law restrictions.

* This list indicates the common uses for which the drug is prescribed. Some drugs are prescribed for more than one condition.

[1] An Accu-Chek or OneTouch blood glucose meter will be provided at no charge by the manufacturer to those individuals currently using a meter other than Accu-Chek or OneTouch. For more information on how to obtain a blood glucose meter, call toll-free: 1-800-588-4456. Members must have CVS Caremark Mail Service Pharmacy benefits to qualify.

[2] A medical exception process is in place for specific clinical circumstances that may require continued coverage for one of these specific products: Freestyle diabetic test strips and Oxytrol. If your doctor believes you have a specific clinical need for one of these products, he or she should fax a medical exception request to toll-free: 1-866-443-1172. Your plan may choose to provide the medical exception process to all medications on this list.

[3] Some dosage forms and/or strengths may not have generic availability.

EXPRESS SCRIPTS®

2014 Drugs Not Covered

As of Jan. 1, 2014, the excluded medications shown below are not covered on the Express Scripts drug list.* In most cases, if you fill a prescription for one of these drugs after Jan. 1, you will pay the full retail price.

Take action to avoid paying full price.
If you are currently using one of the excluded medications, please ask your doctor to consider writing a new prescription for one of the following safe and effective covered alternatives.

Drug Class	Excluded Medications	Covered Alternatives
ANTINEOPLASTIC/ IMMUNOSUPPRESSANT Biologics – Injectable Tumor Necrosis Factor Antagonists and Other Drugs for Inflammatory Conditions	Cimzia, Simponi, Stelara, Xeljanz	Enbrel, Humira
AUTONOMIC & CENTRAL NERVOUS SYSTEM Interferon Beta Medications for Multiple Sclerosis	Betaseron	Avonex, Extavia, Rebif
Long-Acting Opioid Oral Analgesics	Avinza, Exalgo, Kadian	morphine sulfate ER, oxymorphone ER, Nucynta ER, Opana ER, Oxycontin
CARDIOVASCULAR Angiotensin II Receptor Antagonists + Diuretic Combinations	Edarbi/Edarbyclor, Micardis/Micardis HCT, Teveten/Teveten HCT	candesartan/hydrochlorothiazide (HCTZ), irbesartan/HCTZ, losartan/HCTZ, valsartan/HCTZ, Benicar/HCT
DIABETES Blood Glucose Meters & Strips	Abbott (Freestyle, Precision), Bayer (Breeze, Contour), Nipro (TRUEtrack, TRUEtest), Roche (Accu-Chek)	LifeScan (OneTouch)
Dipeptidyl Peptidase-IV Inhibitors & Combos	Jentadueto, Kazano, Nesina, Tradjenta	Janumet, Janumet XR, Januvia, Kombiglyze, Onglyza
Incretin Mimetics (Glucagon-Like Peptide-1 Agonists)	Victoza	Bydureon, Byetta
Insulins	Novolin	Humulin
	Apidra, NovoLog	Humalog
EAR/NOSE Nasal Steroids	Beconase AQ, Omnaris, Rhinocort Aqua, Veramyst, Zetonna	flunisolide, fluticasone propionate, triamcinolone acetonide, Nasonex, Qnasl
ENDOCRINE (OTHER) Androgen Drugs (Topical Testosterone Products)	Fortesta, Testim	Androgel, Axiron
Growth Hormones	Nutropin/Nutropin AQ, Omnitrope, Saizen, Tev-Tropin	Genotropin, Humatrope, Norditropin

*These changes apply to most Express Scripts national drug lists; does not apply to Medicare plans.

Continue on back ❯❯

Continued

Drug Class	Excluded Medications	Covered Alternatives
IMMUNOLOGICAL Interferons	Pegintron	Pegasys
OBSTETRICAL & GYNECOLOGICAL Ovulatory Stimulants (Follitropins)	Bravelle, Follistim AQ	Gonal-f
OPHTHALMIC Antiglaucoma Drugs (Ophthalmic Prostaglandins)	Zioptan	latanoprost, travoprost, Lumigan, Travatan Z
RESPIRATORY Epinephrine Auto-Injector Systems	Auvi-Q	EpiPen, EpiPen Jr
Pulmonary Anti-Inflammatory Inhalers	Alvesco, Flovent Diskus/HFA	Asmanex, Pulmicort Flexhaler, QVAR
Pulmonary Anti-Inflammatory/ Beta Agonist Combination Inhalers	Advair Diskus/HFA, Breo Ellipta	Dulera, Symbicort
Beta-2 Adrenergics (Short-Acting Inhalers)	Maxair Autohaler, Proventil HFA, Xopenex HFA	Proair HFA, Ventolin HFA
UROLOGICAL Erectile Dysfunction Oral Agents	Levitra, Staxyn	Cialis, Viagra

Additional covered alternatives may be available. Costs for covered alternatives may vary. Log on to ***Express-Scripts.com/covered*** *to access cost-savings tools that provide pricing and coverage information for specific medications. Other prescription benefit considerations may apply.*

Excluded Medications/Products at a Glance

Abbott Meters & Strips (Freestyle, Precision)
Advair Diskus/HFA
Alvesco
Apidra
Auvi-Q
Avinza
Bayer Meters & Strips (Breeze, Contour)
Beconase AQ
Betaseron
Bravelle
Breo Ellipta
Cimzia
Edarbi/Edarbyclor
Exalgo
Flovent Diskus/HFA
Follistim AQ
Fortesta
Jentadueto
Kadian
Kazano
Levitra
Maxair Autohaler
Micardis/Micardis HCT
Nesina
Nipro Meters & Strips (TRUEtrack, TRUEtest)
Novolin
NovoLog
Nutropin/Nutropin AQ
Omnaris
Omnitrope
Pegintron
Proventil HFA
Rhinocort Aqua
Roche Meters & Strips (Accu-Chek)
Salzen
Simponi
Staxyn
Stelara
Testim
Teveten/Teveten HCT
Tev-Tropin
Tradjenta
Veramyst
Victoza
Xeljanz
Xopenex HFA
Zetonna
Zioptan

If you have any questions, please call the number on your member ID card.

Express Scripts manages your prescription benefit for your employer, plan sponsor or health plan.

Attachment 3 – Mercer's Step Therapy Analysis

MERCER

Step Therapy Analysis

Maryland Health Care Commission

December 10, 2013

TABLE OF CONTENTS

INTRODUCTION

In the 2013 Maryland legislative session Senate Bill 746/House Bill 1015 that mandated step therapy protocols in the fully insured healthcare market was introduced but was not passed. While the bill technically included services other than prescription drugs, it was the proposed protocols pertaining to prescription drug step therapies that were the source of major discussions and disagreements.

Step therapy is an approach to managing prescription drug cost while ensuring quality and safety by using criteria that the clinicians and payors agree upon for specific therapeutic classes and drugs. Step therapy as defined by Medicare "is a process whereby prescriptions are filled with an effective, but more affordable medication (Step 1). When appropriate, a more costly (Step 2) medication can be authorized if the Step 1 prescription is not effective in treating the condition." [1] If the first step drug proves to be not clinically effective, or if the patient experiences undesired side effects, then the patient can "step up" to a more expensive prescribed drug that will be covered by the plan.

The Maryland Health Care Commission (MHCC) retained Mercer to assist in facilitating a discussion with both the provider and health plan communities regarding step therapy protocols. The goal of this study is to provide a recommendation sensitive to the concerns of both parties to define mutually agreeable step therapy protocols that deliver clinically effective and affordable care.

To help achieve the long term goal, and provide for a more open discussion, two separate meetings occurred: one with providers and one with payors. Two physicians and a government relations representative, represented the Maryland State Medical Society and delivered the perspectives of the provider community at the first meeting. Representatives from Aetna, CareFirst, Coventry, Kaiser and United Healthcare, plus two of their government relations representatives provided the perspective of the major health plans while CVS/Caremark, Express Scripts and the pharmacy benefit managers (PBM) trade group provided the perspective of the PBMs at the second meeting. Representatives from MHCC and Mercer (including a medical doctor and a pharmacist) actively participated in each meeting.

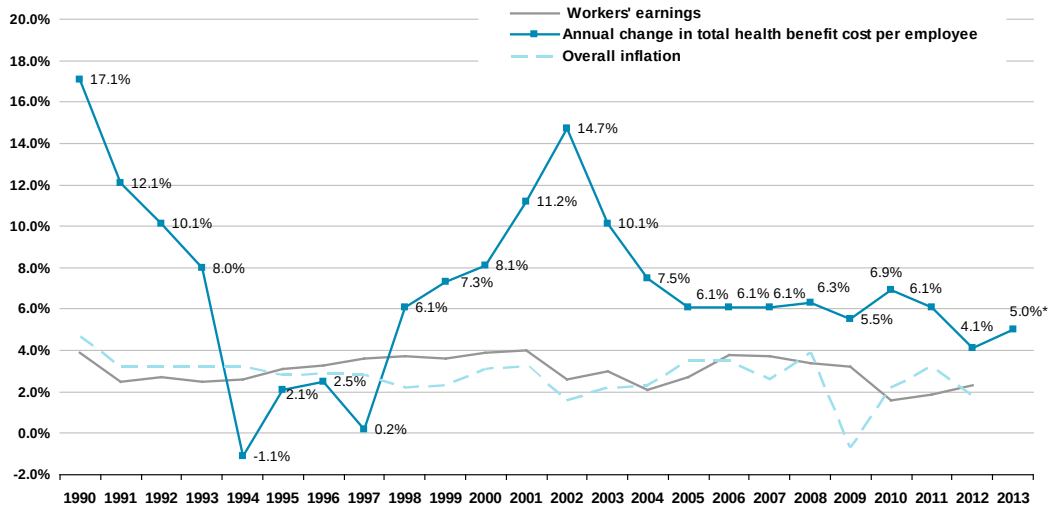
Following these meetings, Mercer forwarded a survey to the major health plans and PBMs for the purpose of gathering more detailed information on existing practices, administration, scope and effectiveness of existing step therapy programs in the industry. We received responses from all the carriers and some PBMs, although not all the entities provided information for all of the questions. The following pages reference the feedback received during the meetings and subsequent survey; identify the major issues from each party's perspective; and our ideas for discussion and consensus.

[1] http://www.q1medicare.com/PartD-Medicare-PartD-WhatIsStepTherapy.php

BACKGROUND: PHARMACY TRENDS AND COST DRIVERS

While increases in recent years have slowed, health insurance costs have increased faster than general inflation and workers earnings, twenty-one out of the last twenty-four years. This is shown on the following chart reflecting the most recent results of Mercer's National Survey of Employer-Sponsored Health Plans:

History of Changes in Total Health Benefit Costs Per Employer versus Workers Earnings and Overall Inflation



*Projected
Source: Mercer's National Survey of Employer-Sponsored Health Plans; Bureau of Labor Statistics, Consumer Price Index, U.S. City Average of Annual Inflation (April to April) 1990-2012; Bureau of Labor Statistics, Seasonally Adjusted Data from the Current Employment Statistics Survey (April to April) 1990-2012.

Increased spending on prescription drugs continues to be a major force in the rising costs of employer-sponsored health benefits. In 2010, $300 billion was spent on prescription drugs in the United States, an increase of $137 billion since 2001. Of particular note are specialty drugs, used to treat chronic and complex conditions such as multiple sclerosis, hemophilia, hepatitis and cancer, which represent approximately 1% of the prescriptions but 35% of the pharmacy costs. These medications are often produced through biotechnology and carry a high cost.

Plan sponsors have successfully weathered drug cost increases over the past 10 years through a combination of traditional pharmacy utilization and cost management tools including tiered cost-sharing, prior authorization, step therapy, mail-order plans, increased use of generics, and case management. Even if they have maximized all of these opportunities, they will need to deploy new tactics to address some of the biggest cost drivers over the next few years at which time, a swell of costly specialty drugs (such as

biologics) are expected to enter the pipeline, and a drop in the number of blockbuster drugs going off patent.

As more high cost drugs come on the market, step therapy is being increasingly utilized to ensure that only the most clinically and cost effective drugs are being utilized. Step therapy is commonly adopted for routine drug categories such as proton pump inhibitors, cholesterol medication, antidepressants, and drugs to treat high blood pressure.

DEFINITION OF STEP THERAPY

The term step therapy, also known as fail-first, is a process or protocol implemented by a health plan or insurer that is associated with prescription drug utilization management. The basic concept behind step therapy is to provide the member with the most cost-effective and safest treatment, which is often a generic medication, before progressing to a more costly, therapeutic equivalent, only if the current treatment is not effective.

While there is no universal definition of step therapy, there are strong similarities in the various definitions of step therapy, such as:

- Step therapy as defined by Medicare "is a process whereby prescriptions are filled with an effective, but more affordable medication (Step 1). When appropriate, a more costly (Step 2) medication can be authorized if the Step 1 prescription is not effective in treating the condition." [2]
- Mercer, in its publication "Hot Topics in Health Care: Pharmacy Benefits", defined step therapy as a "requirement that certain drugs be used only after other "first-line" drugs (usually generics or preferred brands) have been tried and proven ineffective"[3]
- Maryland Senate Bill 746/House Bill 1015 defined step therapy as a "protocol that establishes a specific sequence in which:

  (1) Prescription drug or devices that are medically appropriate for a specified medical condition and a particular patient are to be prescribed and
  (2) A preferred prescription drug or device is prescribed in the sequence."[4]

Step therapy may also be considered in whole or a part of a preauthorization/prior authorization process, which may also require the prescribing provider to confirm to the plan or insurer that an alternative medication or medications have been unsuccessfully tried by the patient before coverage for the prescribed medication is approved.
The primary reason that health plans or insurers implement a step therapy or fail first process is to help manage the rising cost of prescription drugs, specifically for drugs in therapeutic classes where generic options are available.

On page 12 is a process map that reflects the operational flow of most step therapy programs.

[2] http://www.q1medicare.com/PartD-Medicare-PartD-WhatIsStepTherapy.php

[3] "Hot Topics in Health Care: Pharmacy Benefits", Mercer, LLC, 2008

[4] Maryland Senate Bill 746, introduced by Senator Middleton, February 1, 2013, Maryland House Bill 1015, introduced by Delegates Bromwell and Kach, February 8, 2013

As indicated previously, Mercer conducted a survey of health plan providers and PBMs regarding a number of key issues related to step therapy. Table 1 highlights the aggregate responses we received regarding some of these key issues as well as the various definitions and protocols that define their step therapy process.

Table1: Step Therapy Protocols – Carrier Survey Responses

Key Question	Call Scheduled
Definition of Step Therapy	The majority of the carriers have similar definitions for step therapy, which includes a program promoting the use of lower cost drugs before higher cost ones are utilized.
Number of Drugs in a step therapy program	The number of drugs varied widely from carrier to carrier ranging from no drugs to several hundred.
Number of Therapeutic Categories	There was great variability in the number of classes from the carriers, ranging from six to 23.
Number of Steps	The majority of the carriers limit their step therapy to no more than one step (a few use two steps).
Grandfathering Protocol	Variability exists from carrier to carrier on whether an existing member who has tried step therapy must be subject to step therapy again
Peer to Peer access to discuss exceptions	All carriers stated that peer to peer access was available.
Amount of savings from step therapy programs	Savings estimates were available from only one carrier. Others did not track or considered this information to be confidential.

Prevalence of Step Therapy

A number of surveys address the prevalence of step therapy programs from different perspectives. Large and small employer market data is included. Large market data provides directional insight into overall healthcare industry trends.

- In a review of the literature completed in 2010, nearly 60% of commercial payors reported having one or more step-therapy programs.[5]

- Based on findings from the Mercer Annual Survey of Employer Sponsored Health Plans in 2012, almost half (49%) of large employers (500 or more employees) had some type of step therapy program in place.[6] In addition, the same survey showed that 32% of large employers in Maryland have incorporated step

[5] BR Motheral. "Pharmaceutical Step-Therapy Interventions: A Critical Review of the Literature". The Journal of Managed Care Pharmacy, Vol 17, No. 2, March 2011

[6] Mercer. "Annual Survey of Employer-Sponsored Health Plans: 2012". April, 2013

therapy.[7] The data includes both fully insured and self-insured plans. While the Mercer survey data covers the entire market including large employers, and recognizing this study focuses on the fully insured market which tends to cover medium and small employers, it still provides valuable insights into the prevalence of step therapy practices.

- The 2012-2013 Takeda sponsored, Pharmaceutical Benefit Management Institute pharmacy industry survey also provides prevalence data on step therapy. Table 35 from this study shows the percent of plans incorporating some type of step therapy has increased from 56% in 2011 to 65% in 2012.[8]

Table 35. Use of Utilization Management Tools

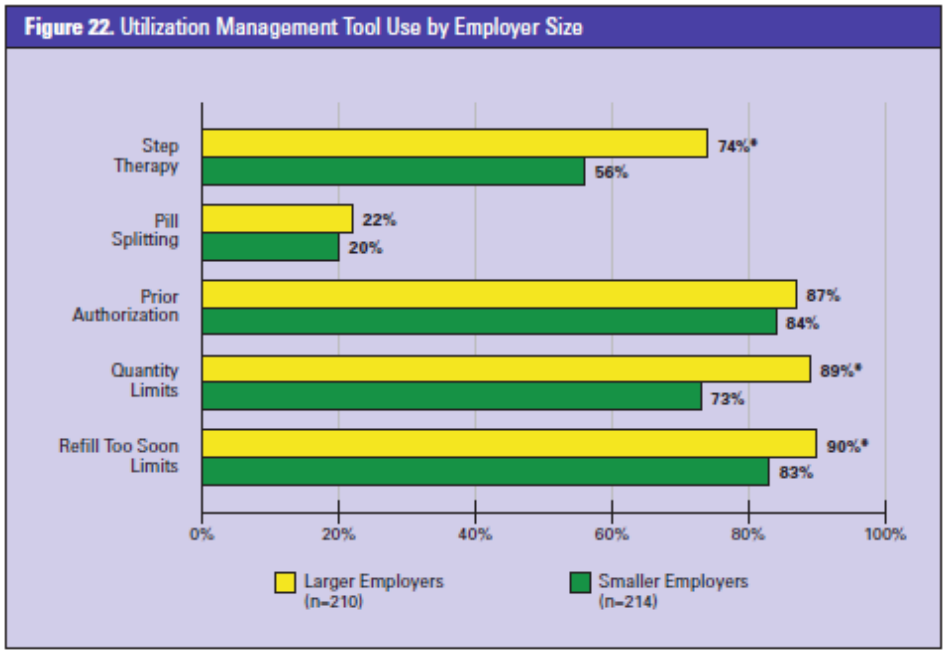
Utilization Management Tool	2012 (n=424)	2011 (n=274)
Prior Authorization	86%	76%
Refill Too Soon/Supply Limit	86%	72%
Quantity Limits	81%	74%
Step Therapy	65%	56%
Pill Splitting	21%	25%

- Due to the reluctance of PBMs and managed care organizations to offer specific numbers as requested in Mercer's survey, there is only a range in the percentage of members in fully insured plans that may be on drugs subject to step therapy protocols.
- In addition, when comparing step therapy prevalence by employer size, Figure 22 from this study indicates 74% of larger employers and 56% of smaller ones have adopted step therapy. [9]

[7] Ibid.

[8] Takeda Pharmaceuticals USA, Inc. "2012-2013 Prescription Drug Benefit Cost and Plan Design Report" Pharmaceutical Benefit Management Institute. 2013

[9] Ibid.



- In the *Large Employers 2013 Health Plan Design Survey,* when asked about what techniques employers will use to manage their traditional pharmacy benefits in 2013, the three most popular techniques reported were step therapy (73%), prior authorization (71%) and quantity limits (70%). [10]
- Table 3 displays the outcomes for step therapy that were assessed in a critical review of evidence-based literature on step-therapy interventions. The review includes seven studies of commercial populations and the outcomes measured.[11] It's clear from this review that cost effectiveness, medication adherence/compliance, and patient/provider satisfaction have only been empirically measured for four drug classes: antidepressants, antihypertensives, NSAIDs/COX-2 inhibitors, and proton pump inhibitors. [12]

[10] National Business Group on Health/Towers Watson, 17th Annual Employer Survey on Purchasing Value in Health Care, *Survey Report,* March 2012.

[11] BR Motheral. "Pharmaceutical Step-Therapy Interventions: A Critical Review of the Literature". The Journal of Managed Care Pharmacy, Vol 17, No. 2, March 2011

[12] BR Motheral. "Pharmaceutical Step-Therapy Interventions: A Critical Review of the Literature". The Journal of Managed Care Pharmacy, Vol 17, No. 2, March 2011.

TABLE 3 Summary of Outcomes Assessed for Step Therapy Across Different Drug Classes and Populations[a]

	Drug Cost Savings	Medication		Appropriate-ness of Use	Medical Spend	Clinical Outcomes	Patient/Provider Satisfaction/ Understanding
		Initiation	Adherence				
Commercial							
Anticonvulsants							
Antidepressants	X	X	X		X		X
Antidiabetics							
Antihypertensives	X	X	X		X		
Antipsychotics							
Hypnotics							
Leukotriene modifiers							
Multiple sclerosis treatments							
Nasal steroids							
NSAIDs/COX-2 inhibitors	X	X					X
Proton pump inhibitors	X	X					X
Statins							
Stimulants to treat ADHD							
TNF-blockers							
Triptans							

Mercer surveyed five health plans that utilized step therapy to identify the therapeutic classes for which step therapy applies. In contrast to what is established in the empirical literature, wide variations were identified both in the number of therapeutic classes for which step therapy applies as well as the number of steps outlined in the step therapy protocols. The five health plans reported having between seven and 23 therapeutic categories with a step-therapy program. On the high end of the spectrum, one health plan reported having 430 unique drugs with one step therapy protocol and 31 drugs with more than one step therapy protocols. [13]

According to the carrier/PBM survey conducted by Mercer, the following categories contain drugs that may be subject to a step protocol: Acne, ADHD, Allergies, Alzheimer's, Anticonvulsants, Anti-diabetic, Antiviral, Blood Pressure, BPH, behavioral health, Cancer, Cholesterol, Crohn's Disease, Corticosteroids, Depression, Dermatologic Conditions, Glaucoma, Gout, Growth Hormones, Insomnia, Infertility, Migraines, Multiple Sclerosis, Osteoporosis, Overactive Bladder, Pain, Restless Leg Syndrome/Parkinson's Disease, Rheumatoid Arthritis, and Stomach acid conditions, [14]

In addition, the prevalence of step therapy in other states varies widely. There are 23 states that have proposed legislation and only 10 states have active regulation in place. Two of those ten states with active legislation, specifically Florida and Nevada, have step-therapy related legislation that applies to their Medicaid populations only.[15] The remaining 13 states' bills have either stalled in the legislation process, did not pass, or have been vetoed. [16]

[13] Mercer Survey Questions regarding Step Therapy for Managed Care Organizations and Pharmacy Benefit Management Companies, submitted July 2, 2013.

[14] Mercer Survey Questions regarding Step Therapy for Managed Care Organizations and Pharmacy Benefit Management Companies, submitted July 2, 2013.

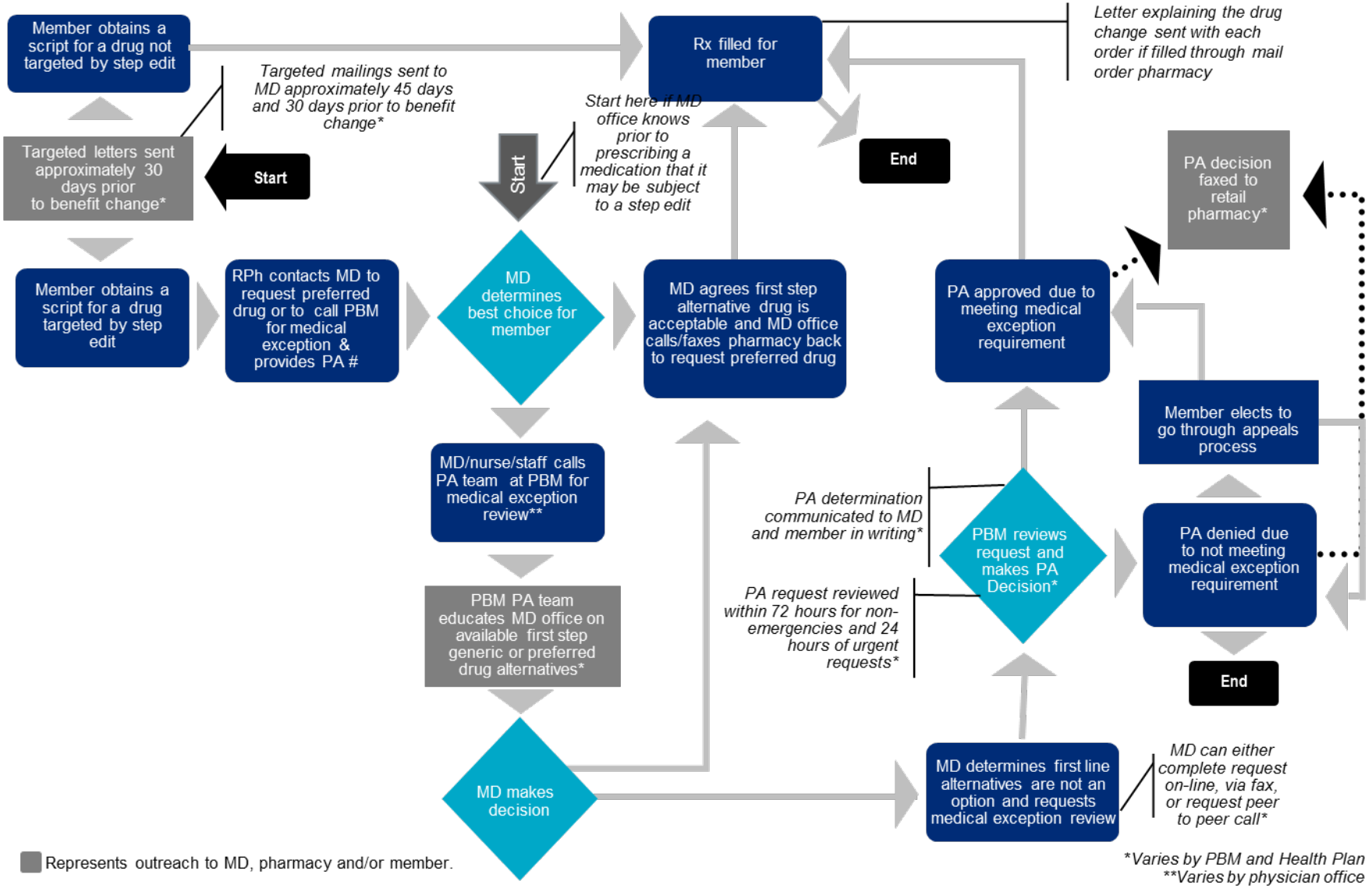
[15] www.firstfailhurts.org

[16] Ibid.

The table below provides a summary where legislation has been enacted.

	Connecticut	Delaware	Florida	Illinois	Iowa	Kentucky	Louisiana	Mississippi	Nevada	Texas
Physician prior authorization overrides step therapy protocol		x	Medicaid only							
Clear and convenient process to override restriction by demonstrating ineffectiveness or possible adverse reaction						x	x	x		
Duration no longer than the customary period for the medication when demonstrated ineffective							x			
Establish Pharmacy Monitoring Program to…respect and preserve the integrity of the patient's treatment relationship with the patient's health care providers					x					
Max. duration if drug seen as ineffective						30 days		30 days		
Prohibit requiring insured to use, prior to using a brand name prescription drug prescribed by a licensed physician for pain treatment, any alternative brand name prescription drugs or over-the-counter drugs.	Pain med. only									
Conform to evidence-based practices per peer-reviewed medical and pharmaceutical literature										
Medical assistance programs may not require prior authorization, step therapy, generic substitution, or quantity limits without express written or oral notification and the documented consent of the practitioner and the patient.				Immunosuppressant med. only						
Establish and manage program of step therapy and prior authorization for prescription drugs.			Medicaid only						Medicaid only	
Exception process action limit						48 hours				
Physician's determination of medical necessity overrides										x

Step Therapy Flow Chart



KEY ISSUES OF CONCERN FOR PROVIDERS:

From a provider's perspective, step therapy can limit the initial choices of drugs for their primary treatment options. This occurs since the provider must prescribe a therapeutically equivalent alternative treatment first and demonstrate that the treatment is not effective for the given patient.

The State of California recently performed a study on step therapy.[17] In the section of the study on impact of step therapy protocols on medical effectiveness, the authors concluded that "There is insufficient evidence to determine whether fail-first protocols, regardless of the number of steps, directly affect health outcomes. The absence of evidence is not evidence of no effect. It is an indication that the impact of fail-first protocols on health outcomes is unknown". [18]

Key issues associated with step therapy as articulated by Maryland providers that were present include:

1. **Limiting step therapy to a maximum of 30 days, and sometimes less depending on the drug, the diagnosis and other factors:** Providers articulated a strong belief that regardless of how many steps are involved with a step therapy protocol, a patient should not have to try any one drug for more than 30 days (and depending on the condition or the drug maybe less time and in a few instance, sometimes more) before stepping to a drug that the provider deems the best therapeutic alternative.

2. **Ready access to a clinical peer to discuss possible exceptions and appeals and timely response to inquiry:** Providers expressed frustrations with the exception process, poor communication and the difficulty in reaching payor clinical staff to discuss exception requests and appeals. They requested a simple and expeditious protocol to obtain a peer to peer review on exception requests and appeals. They also mentioned that requests for peer to peer could either go unanswered or be answered after a long period of time. The providers acknowledged that some prescribers do not have a good understanding of the cost differences between a prescribed medication and a proposed alternative and suggested some would be happy to change the recommended alternative medication when armed with the facts through a peer to peer discussion.

3. **Simplification of Step therapy rules and administration:** Providers pointed out that the health plans and pharmacy benefit managers (PBM) have different approaches to step therapy, different formularies, and different protocols. In some instances, the same payor may have different protocols for Maryland-based fully insured business, self-insured plans, and out-of-state plans. In addition, these protocols are subject to change. From the provider

[17] http://chbrp.ucop.edu/index.php?action=read&bill_id=151&doc_type=3

[18] Ibid.

perspective, the processes are burdensome and inflexible. The problems are exacerbated when a patient changes health plans. These concerns did not come as a surprise as the physician and office staff are faced with dealing with multiple coverage requirements unique to each health insurance program.

4. Establishment of common grandfathering protocols: Providers pointed out that in cases where a member changes health plans or employers, or where there is a formulary change, an existing medication is working effectively the member may still need to make a change and "step back" depending upon the grand-fathering rules. This can create a disruption in care. Health plan and PBMs establish a look-back period for grand-fathering and that timeframe varies widely among the carriers. These protocols are a source of confusion for providers and members and can cause a good deal of extra paperwork. In addition the look-back time period for grandfathering processes differs by carriers and is dependent on complete, clean and consistent data transfer between health plans/pharmacy benefit managers.

5. Establishment of Practice protocols that reflect the input of the treating physician in specific cases and in general the national standards of practice: Physicians questioned the payors' treatment protocols on two levels; 1) on whether guidelines were developed and updated using currently accepted practice standards established by nationally recognized organizations and 2) the weight of financial impact vs. therapeutic outcomes. In specific instances, providers favored relying more heavily on the judgment of the treating physician. In general, the physicians described a preference for relying on practice standards outlined by the medical society or clinical specialty group rather than the payor's guidelines.

In general providers acknowledged the need for step therapy due to variations in practice patterns as well as the necessity of financial controls on branded high cost drugs. This is an important issue that forms a basis for common ground among the provider and the payors.

KEY ISSUES OF CONCERN FOR PATIENTS:

Step therapy is a long-established strategy intended to ensure the use of the most clinically sound and cost-effective drug. Along with prior authorization, quantity limits, and pharmacy benefit tiering, step therapy also is an accepted approach to the challenge of balancing clinical efficacy and cost-effectiveness in the treatment of patients with chronic and other conditions. Many recognize that the goal of this policy to control costs makes sense, but often find that when the policy is applied to the patient, a different reality appears.

1. Patients point to monetary, physical, and psychological distress Step therapy programs impose on patients..
2. Patients see Step therapy policies as increasing healthcare costs as it could potentially require them to end the use of a successful treatment

The rapid growth in the prescribing of biologics adds further confusion to the debate. With respect to the requirement that a traditional therapy (or even a specific biologic product) be used before the prescriber can employ the preferred treatment have caused both patients and providers to voice concern. Biologics manufacturers caution that specialty drugs often are not interchangeable, and payers assert that evidence of long-term safety and efficacy of biologics is often lacking, to say nothing of the costs involved, which cannot be ignored. In 2012, almost 40 new biologics earned FDA approval with dozens more in Phase 3 trials or undergoing FDA review. For third-party payers, this avalanche of new therapies comes at a time when purchasers are trying to stabilize their costs of providing healthcare benefits.

MHCC sought input from patient groups on how Step therapy could be implemented in a manner that would preserve carriers ability to direct patients to the most cost effective treatments while enabling patients to have easier access to alternative treatments. Advocates contend that patients that suffer from conditions that are highly uncommon or conditions in which treatment protocols significantly vary face special challenges under Step therapy protocols.

Immune deficiency diseases fall in the category of a rare disease for which expensive biologics are available. During the legislative session, the advocacy arm of the Immune Deficiency Foundation had aggressively supported passage of the legislation. MHCC met with representatives from the Immune Deficiency Foundation to hear their views on Step Therapy. The Immune Deficiency Foundation is the national patient organization dedicated to improving the diagnosis, treatment and quality of life of persons with primary immunodeficiency diseases. Their advocates pointed to challenges patients that suffer from a primary immunodeficiency disease who are unable to fight off common viruses, bacteria or fungi because their immune system does not produce antibodies necessary to fight disease. The group pointed to the challenges patients encounter in treating their condition with Immunoglobulin (Ig) replacement therapy which consists of a blood plasma product from pooled plasma donations. The challenge is that there are 12 different Ig products. The FDA recognizes that some of the products are not clinically

equivalent and therefore interchangeable. The group contended that subjecting patients needing Ig to Step therapy puts patients at risk. The advocates supplied peer reviewed scientific literature that showed that forcing patients who are stabilized to “switch” their therapies to a new product could lead to some of those patients suffering mild tto sever adverse reactions.

The Commission also received a number of letters that raised similar concerns regarding Step Therapy policies for certain drugs used in the treatment of epilepsy. These drugs were not biologics or particularly expensive. Several patients contended that some generic versions of branded drugs were not clinically equivalent. These letters pointed to controversy surrounding generic substitution of branded antiepileptic drugs (AEDs). Breakthrough seizure activity have been reported with conversion from brand name (Keppra) to generic levetiracetam. MHCC was not able to identify any evidence that these FDA differences had been documented by the FDA.[19]

[19] The Food and Drug Administration (FDA) considers generic medications to be therapeutically equivalent to their corresponding brand name formulation when the generic meets bioequivalence criteria. Because the FDA relies on voluntary reporting of adverse events from health-care professionals and consumers to their MedWatch program, underreporting makes it difficult to quantify the significance of brand to generic switches, and, equally important, generic to generic switches.

KEY ISSUES OF CONCERN FOR PAYORS

From the payor's perspective, step therapy offers an opportunity to provide lower cost but similar quality drugs as an initial step to manage a patient's condition. Should that drug prove to be not clinically effective, the physician has the ability to request a change in the drug after a specified time period (or less if the patient's condition requires it).

1. **Limitation of step therapy to a maximum of 30 days, and sometimes less depending on the drug, the diagnosis and other factors.** All of the payors responded that they had a 30 day or less requirement to step up. Some indicated certain therapeutic categories could have less than a 30 day requirement based on clinical appropriateness.

2. **Ready access to a clinical peer to discuss possible exceptions and appeals and timely response to inquiry Standard Protocol for Speaking Directly with a Pharmacist or Medical Director to discuss an exception:** From the meeting with providers, the issue of established turnaround time guidelines for health plans/PBMs to review step therapy requests by providers creates significant dissatisfaction from the members and providers. From the survey responses of the carriers, it is clear that there are no uniform turnaround times established across the board and that in the cases where turnaround time policies exist, they are not tracked and reported on. Typically, the exception process requires a provider to call in and speak directly with a pharmacist or medical director or to use the portal in order to have the exception approved and processed. A standard turn around time for all carriers should be considered.

   Carrier A: Physicians can ask to speak to a pharmacist and be connected at any time, 24 hours a day, seven days a week. Contact with a Medical Director can be scheduled by appointment.

   Carrier B: Any provider can ask to speak to a pharmacist or medical director and they will receive a call from the pharmacist or doctor.

   Carrier C: "Peer to peer" (P2P) conversations can occur "upon request at any point in either the initial coverage review process or the appeals process". During the P2P, a conversation is arranged between the prescriber and the clinical decision maker. On initial coverage review, that conversation would take place with the clinician making the initial determination (or an equivalent clinician team member, if the decision maker is no longer available when the request is received). If a peer to peer conversation is requested during the appeals process, it is typically performed as part of the appeal. If it is requested prior to making the final decision on the appeal, every effort is made to have the conversation take place at a time mutually agreeable to both the prescriber and the clinician reviewer before the final decision is made, if regulatory turnaround time requirements allow. If regulatory requirements do not allow, the appeals decision

is rendered within regulatory requirements and the P2P takes place as soon as possible afterwards. If the P2P changes the appeals decision (non-coverage to coverage), the case is reopened and a revised decision letter sent to member and prescriber, If the physician requesting P2P requests a conversation with specific clinical specialty, every effort to accommodate is made to do so, as regulatory time frames allow. Since P2Ps are incorporated into either coverage reviews or appeals, this vendor does not track statistics on P2Ps

The findings of the survey show that some health insurers or PBMs have processes in place to facilitate conversations between providers and medical directors/pharmacists for the situation in which a provider is requesting an exception to the step therapy protocol. However, it's unclear what timelines are in place to ensure that when a request is submitted to speak with a medical director, the provider is contacted in a timely manner. Aside from Carrier C, it's unclear what documentation (if any) is provided to the member/provider after the exception process has been resolved.

Appeals Process

On average, the carriers that were surveyed reported between 9% and 23% of cases that were reviewed through the exception request process were denied. Therefore roughly 75-90% are approved. These cases are then subject to an appeals process, which can vary in turn-around-time and steps involved by a carrier. Two examples of appeals processes are described below:

Case #1: When a member and their provider receive notification that a request for a Step Therapy medication has been denied, steps for filing an appeal (including an expedited appeal if situation is such that a delay in determination could jeopardize the member's life or return to normal function) are included in that written notification. Members, healthcare providers or any other representative so designated by the member (family member, attorney or other advocate) may represent the member in their appeal.
Appeals are typically received by mail or fax, although urgent appeals may be initiated by a phone call. Once an appeal is received, it is reviewed to determine urgency, The nature of the appeal and all regulatory requirements around the appeal are documented, including who needs to perform the review (specialty and licensure) and due date to meet regulatory requirements. Once the requirements are established, the appeal is sent to the appropriate clinical reviewer, who reviews all pertinent clinical records, including any medical records supplied, supporting letters from member, attending clinician, medication claims history, etc.

Case #2: A patient who has received an initial coverage review may ask for an appeal of this decision by making a written or oral request. To do so, a customer service representative will instruct the patient to either provide the benefit review

request verbally or to submit it in writing. All oral requests are documented in writing, and documentation is maintained in the case file. All oral appeal requests will be transcribed consistent with procedures which detail this activity. The patient or physician will be provided, as appropriate, with a reasonable opportunity to present evidence and allegations of fact or law, related to the issue of dispute, in person as well as in writing or by phone. In the case of an expedited appeal, the opportunity to present evidence is limited by the short timeframe for making a decision.

3. Simplification of Step therapy rules and administration: Drugs are typically grouped into categories based on costs, and step therapy protocols are developed under the guidance of independent doctors, pharmacists, and other medical experts.[20] Each payor has its own approach. Differences exist in formularies, grandfathering practices, the number of therapeutic classes subject to step therapy, number of steps within a therapeutic class, trial durations, override practices, and system capabilities. In addition, a given payor will typically have different protocols for its insured business depending on contract situs, i.e., each state may have specific requirements for contracts located within the state, and also its self-insured business. For the most part, the payors have little control over these differences.

The payors referenced several tools and policies already in place to simplify the step therapy process for providers serving patients with insured programs in Maryland:

The carriers have established web portals as a result of recent legislation, in an effort to provide real time access to their various plan designs and create an electronic method to communicate between provider and payor. This currently web portal can serve as a vehicle to standardize the step therapy contact and request process including exception requests and appeals. However, to date, these web portals have low utilization.

Payors expressed that they had educated physicians on polices, procedures, and operations related to exception requests many times, and that physicians still do not seem to understand how to best navigate the system.

4. Establishment of common grandfathering protocols: Although grandfathering processes seem to be in place across the board for the carriers included in the survey, the actual practices related to particular drug classes and look back time periods are unclear. As noted in the meetings with providers, the variation and ambiguity of the grandfathering approaches creates unnecessary confusion and additional work for the member and provider. Below are the carrier responses to different scenarios that would prompt a grandfathering process to activate:

Situation 1: If a patient's insurance changes from a competitor to one of your products;

[20] Express Scripts. "Frequently Asked Questions About Step Therapy". 2008

Carrier A: will make every effort to request a patient's drug history from the prior PBM, if it is available. If the logic and claims data is able to be read, the PBM will honor that.

Carrier B: As a practical matter, the request will be stopped for review because the new provider will not have prior claims available in the system for review. The member will be able to submit documentation of use of any drug while covered under the other carrier for consideration as part of the review process and that will be considered to the same extent as if the drug has been used while covered.

Carrier C: Decided on a case by case basis.

Carrier D: In general most specialty medications are grandfathered, while non-specialty medications are not. If grandfathering is allowed, this is regardless of whether the patient's employer changes.

Situation 2: If a patient's employer changes, but the patient continues coverage in one of your products;

Carrier A: Unless the patient retains the same health plan and the same patient ID number, grandfathering would not occur because there could be multiple patients with the same information.

Carrier B: This will not cause a disruption of coverage for the drug at issue.

Carrier C: Decided on a case by case basis.

Carrier D: In general most specialty medications are grandfathered, while non-specialty medications are not. If grandfathering is allowed, this is regardless of whether the patient's employer changes.

Situation 3: If there is a formulary or step therapy protocol change;

Carrier A: This would not impact anyone already subject to the step therapy program. There is no disruption for formulary or protocol changes.
Carrier B: Members and providers are notified in advance of any coverage changes. The plan typically notifies members and providers of such changes at least 60 days in advance.

Carrier C: Decided on a case by case basis.

Carrier D: In general most specialty medications are grandfathered, while non-specialty medications are not. If grandfathering is allowed, this is regardless of whether the patient's employer changes.

In order to facilitate a more timely and member-centric solution to dealing with step therapy protocols, it is imperative that legislative bodies understand the variation that exists between the pharmaceutical benefits providers (both PBMs and medical carriers). As is evident in the responses obtained from the carriers, their processes vary not only in comparison to one another, but their policies internally can vary depending on the situation, as exemplified in the grandfathering approach scenarios.

Inherent in the discussion of grandfathering approaches is the issue of exception requests. This process could be simplified by creating an exception process that accounts for the multiple ways a patient may need to opt out of a step therapy protocol. The exception process could also limit repetitive step therapies for a patient when alternatives have already been identified and utilized.

As one carrier responded to the grandfathering approach question, they "will make every effort to request a patient's drug history from the prior provider, if it is available. If the logic and claims data is able to be read the PBM will honor that." This issue of variability between carriers as it relates to look back time periods and obtaining usable data could be resolved if the carriers could establish (1) a set look back time period for which they retain patient records, and (2) a standard format and timeline for transferring data between carriers when an employer group moves from one carrier to the next. While this standardization may work well for large groups, it may have less impact in the individual and small group environment where it is currently uncommon to transfer claims data upon a change in carriers.

5. Establishment of Practice protocols that reflect the input of the treating physician in specific cases and in general the national standards of practice: A couple of carriers responded that their Pharmacy & Therapeutics committee makes the determination about step therapy drugs and criteria. The others mentioned these are made on a case by case basis for each drug, but that safety and efficacy are the first criteria.

CONSIDERATION FOR STEP THERAPY: SUMMARY AND NEXT STEPS

Review of the issues identified above from the provider and payor perspective identifies several possible areas where the constituents have common ground that could be forged to put forth a second iteration of the legislation:

1. It appears that most of the payors agree that the first step of a protocol should not be more than 30 days, and they imply in many cases it is less than 30 days. It is unclear if any of the two step processes require more than 30 days, but since the number of drugs with two steps is much lower than the number with one step, the 30 day limit to step through the therapy process is a possible area of common ground.
2. Ready access to a clinical peer in principle is an area of common ground. The payors articulate that the access exists, however it appears that the providers do not know how to access a clinical peer in many cases either for the initial exception request review or for an appeal.
3. Administrative simplification is an area of concern. The payors clearly stated that they all have their own protcols, drugs on step therapy, and operational procedures for exceptions and they don't seem to have a desire or ability to standardize these across their competitors. There are measures that could be taken to improve this situation including:

    - The carriers can be required through legislation to develop a strategy for provider communication to include the use of existing resources and any new approaches emerging from this initiative.

    - Education sessions co-conducted by plans/PBMs can target physicians and office staff to educate them on how to best deal with step therapy could significantly increase the use of existing resources and minimize the frustration created by various processes/protocols related to step therapy.

    - Increased use of the web portal for exception requests, through education and reminders to physicians and office staff.

4. There is tremendous variation in the grandfathering rules among the payors. Standardization would be difficult but perhaps an online tool would help providers understand these rules better.
5. Improved communication by the carriers on how particularly step therapy rules are set up and why would be helpful. Sharing the clinical evidence behind the rules upon provider request would show goodwill as well as improving credibility for the plans in the eyes of the providers and members.

STEP THERAPY PROTOCOLS AS A COMPONENT OF VALUE BASED INCENTIVE-BASED DESIGNS

MHCC requested that Mercer include a discussion on Value-Based Benefit Design (VBBD) as part of the step therapy discussions. VBBD strategies typically focus on different facets of the health care continuum such as health behaviors, chronic condition management, medications, and provider choice.[21] Value based designs are intended to allow participants to receive a discounted benefit, while encouraging compliance. Step therapy programs are designed to promote more cost effective drugs first before more expensive drugs are authorized. These programs have different intended purposes and are not usually coordinated efforts.

A preferred physician or "gold card" approach was also discussed by providers and health plans. This process would exempt high performing physicians from the step-therapy process requirement. These physicians would be exempt from certain administrative protocols based on their prior performance but their performance would continue to be tracked. Some of the payors said that this type of program had been implemented on a limited basis in areas other than pharmacy and that in theory it might work for pharmacy benefits as well. Physicians were more skeptical, not so much with the concept but rather the fairness of the process for identifying the "gold-carded" providers.

[21] National Business Coalition on Health, http://www.nbch.org/Value-Based-Benefit-Design-Introduction