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Specialty Pharmaceuticals – Utilization Management

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Specialty medications are complicated, treat complicated diseases, and are costly. Yet, even if their cost was to be decreased by 50%, many of the specialty medications would still be too costly either with high copays, or be unaffordable under any circumstance. Hence the use and oversight of Specialty medications is more complex than just cost: effectiveness, risk and cost must be evaluated concurrently. Utilization is actually the great multiplier. No matter the individual cost of a medication, uncontrolled expansion of medication use leads to more drugs, and therefore, higher drug spend. Utilization management of Specialty medications is, thus, a multifactorial process that is as important as cost management.

Human Insulin was the first of the so-called "Specialty Medication." Specialty treatments followed for orphan and previously untreated diseases. Treatments for chronic diseases followed where Specialty medications replaced older small molecules. The major complication was that the cost of these new treatments rivals, and often exceeds, acute care hospital stays. Unfortunately, evidence has not always matched the comparative benefits of Specialty medications over their small molecule counterparts. As a result, the explosion of new Specialty medications has also stimulated the need for strong evidence that these medications are significant improvements over prior therapies. If so, how can they be affordable?

Utilization management of Specialty medications shares many of the same elements that have been used for decades to monitor and manage all treatments; namely, prior authorization, drug utilization review, step therapy, and quantity limits. This paper will examine the approach to utilization management of Specialty medications with the goals of providing a template for providers to participate in this management as well as to understand the metrics applied when these medications are submitted for payment.

Definition

Utilization management is a tool for evaluating therapy for effectiveness while also monitoring for the risk introduced by these treatments. As treatments have become more expensive, utilization management has also become a euphemism for cost control. Yet, utilization management is not without definition. Utilization was defined in the Omnibus Budget Reconciliation Act of 1990, Section 4401, known as Obra 90. This law contained the requirement for prospective drug utilization review that included:[1]

- Therapeutic Duplication
- Drug-Disease Contraindications
- Drug-Drug Interactions
- Incorrect Drug Dosage
- Incorrect Duration of Treatment
- Drug-Allergy Interactions
- Clinical Abuse/Misuse of Medication

In order to implement the Obra 90 requirements tools were developed to "manage" utilization. The motivation for these tools and methods is frequently cost control, but the rationale can usually be anchored to a need for risk management. As a result, Drug Utilization Review (DUR) must cover the prospective, concurrent, and retrospective use of medications throughout the patient's experience. As such, the definition of DUR in Obra 90 has been expanded to include common benefit tools supporting formularies, especially restricted formularies of various designs. Common tools employed by insurers are:

- Maximum Number of Medications Allowed
- Prior Authorization based on usage criteria
- Step Therapy (ST)

- Quantity Limits (QL)
- NDC blocks
- Medication Refill Limits
- Max Dollar Limits

Specialty medications have expanded the need for deployment of these tools and caused payers to reach back to the original tests applied for all therapy: namely, FDA approvals for medications and uses, effectiveness and comparative effectiveness, and tests for risks of these treatments. [Figure 4]

Metrics Used for Management

The approval of Specialty medications has driven the need for merging elements of Pharmacy and Medical benefits. Merging benefits brings its own complications requiring data and metrics to manage these benefits. The broad metrics used by insurers that are applicable for management of Specialty medications in merged medical/pharmacy benefits are [Figures 2, 3]:

- Total Amount Paid overall and by channel
- Per-member-per-month (PMPM) and per-year (PMPY)
- Per utilizer-per-month (PUPM) and per-year (PUPY)
- Location of Service – Paid/claim and PUPM
- Top Diagnoses – Paid/claim and PUPM
- Top providers, specialties, medications, and related procedures – Total paid, paid/claim, paid/unit, PUPM, #Rx PUPM
- Comparative Unit Price and Discount by Channel / Sub-channel – ASP, AWP / WAC, AMP, NADAC and AAC

The list of metrics is dynamic and requires trending as well as benchmark comparisons. Of particular concern is how these metrics are calculated and applied. Standardization by data aggregators, surveyors, and health plans is crucial so that appropriate comparators are applied. These metrics are, and will also be, applied to benefit designs utilizing best-in-class (BIC) and centers of excellence (COE) to improve quality and achieve performance improvement. These designs have been used in medical benefits for some time, so it will be no surprise that the cost as well as complexity of diseases and conditions utilizing Specialty medications as the primary vehicle for management will drive BIC and COE care delivery models. [Figure 1]

Effectiveness and Benefit Compliance

The first consideration for providers and insurers is the effectiveness of Specialty medications and their compliance with benefit definitions. The primary tests used by insurers are:

1. Diagnosis ICD10 Billed vs. Expected ICD10 for the prescribed medication
2. Dosage and duration billed consistent with usage for ICD10 billed
3. Benefit / Formulary compliance

As a result, prescribers and pharmacists must ensure that any Specialty prescription complies with these tests. Utilization management uses these tests to determine if the medication is being used for FDA approved package labeled vs. off-label uses and if benefits cover the diagnosis in the claim. Dosage tests for Specialty require more than the traditional tests for prescribed dosages that are greater/lower than the maximum/minimum labeled dosages. The tests evaluate dosage for the specific condition prescribed as compared to the possible dosages for the multiple conditions that a Specialty medication may treat. In addition, the tests evaluate the dosage when the medications are used in combination as with cancer chemotherapy. The benefit compliance tests must also determine if there is a violation of quantity limits, duration of therapy, and step therapy requirements when applicable. The result of these tests is an approval of a prior authorization; hence it is crucial that prescribers and pharmacists ensure that merged information from medical and pharmacy benefits are accounted for in the prescribing decision.

Specialty medications are often used in concert with other medications and non-medication therapy. As a result, individual medications are not evaluated in isolation, but as part of a regimen. These regimens, especially pertinent to cancer chemotherapy, are evaluated by the three effectiveness tests above as applied to the entire regimen. Evidence-based guidelines assume a significant role in the prescribing, utilization oversight, monitoring, and benefit approval of therapeutic regimens. The use of Specialty medications as solo treatments and as part of regimens places further emphasis on the evidence-based tools applied to benefit approvals. Therefore, prescribers and pharmacists must pay attention to the evidence supporting the use of Specialty medications for various conditions, and must also be familiar with NCI, NCCN, and national guidelines for usage of these medications. Clearly, the cost of these medications requires that they be used when there is significant evidence of benefit and acceptable risk. [Table 1]

Risk

The consideration of risk is not separate, but coordinated with the evaluation of effectiveness. Specialty medications treat high risk conditions like various cancers, hepatitis, and multiple sclerosis. They also contribute higher additional risk than small molecule therapy due to higher probabilities of allergies, adverse drug reactions, and drug-induced conditions. As a result insurers return to Obra 90 tests for claims with inadequate/super

dosages, extended durations leading to unnecessary exposure to medication effects, duplications leading to increased chances of additive side effects, polypharmacy risks for drug-induced problems, and adverse drug interactions. It is incumbent on all providers to include an aggressive plan for surveillance and management of these risk factors in order to minimize overall risk.

Due to the enhanced chances of risk from Specialty and other medications the FDA has required Risk Mitigation and Evaluation Strategies (REMS) from manufacturers for specific medications. By definition "The Food and Drug Administration Amendments Act of 2007 gave FDA the authority to require a Risk Evaluation and Mitigation Strategy (REMS) from manufacturers to ensure that the benefits of a drug or biological product outweigh its risks." When a medication has a required REM the prescriber and pharmacist must fulfill specific requirements for surveillance as well as educating the patient to ensure that the risk of drug-induced problems is minimized. The provider, i.e., physician and pharmacist, certification requirements of each REM add a specific utilization approach to each applicable medication.[2]

Effectiveness / Risk / Affordability

Utilization management of Specialty medications encompasses the broad set of surveillance and management metrics identified above. It could also be argued that Specialty medications must be viewed under the lens of merged medical and pharmacy benefits that require concurrent evaluation of effectiveness, risk and affordability. This type of evaluation requires more information and communication between all providers. Traditional claims information must be supplemented with patient-specific information derived from electronic medical records (EMRs), the results of biometric screening, and patient supplied information from electronic health records (EHRs) and health risk assessment questionnaires (HRAs). A standard language is required to digitally integrate all of this information.

The Unified Medical Language System® (UMLS®) was designed for this purpose as an international standard. As a component of this system the Systematized Nomenclature of Medicine (SNOMED) vocabulary provides a systematic library of medical terms, in computer processing language, "for human and veterinary medicine, to provide codes, terms, synonyms and definitions which cover anatomy, diseases, findings, procedures, microorganisms, substances, etc." The UMLS® also contains RxNORM that contains standard names for drugs that do not change with NDC so that EMRs, drug interaction databases and pharmacy computer system software can talk to each other.[3,4]

All pharmacy computer software and medical EMRs will have to be programmed to communicate in these languages. The result is an international movement of managed care principles into individual patient and population management. Medication Therapy Management (MTM) and Comprehensive Medication Review (CMR) must be cast into these languages and will be enhanced by the integrated data available from the EMRs and HRAs. In addition, laboratory data is undergoing a similar codification and language standardization through the Logical Observation Identifiers, Names and Codes or LOINC®. This standard coding system will help to facilitate the incorporation of laboratory findings into the overall evaluation of care both individually and in populations. This includes the genomic testing required for selection of those Specialty medications used to treat applicable diseases.

However, while common languages are being deployed there are utilization tests that incorporate elements of effectiveness, risk, and the resultant affordability of Specialty medications. Surveillance for drug-induced disease, and adverse drug reactions, is paramount for new clinical findings in diseases treated with Specialty medications as well as the first consideration in the differential for new symptoms in elderly patients. In addition, the universe of opportunities for drug interactions now includes medications used in both medical and pharmacy environments. This merging of experience also reflects usage, or lack thereof, where patients take drug holidays and fail to adhere to prescribed regimens. The complexity of regimens including Specialty medications, enhanced side effects, and affordability all contribute to usage concerns.

The metrics that insurers may use to evaluate the coordinated utilization of Specialty medications are commonly calculated from codes in claims data, and while there is no generally accepted metric profile at present, many metrics are reported. Providers may receive some or all of this information from Health Plans or Pharmacy Benefit Managers (PBMs). For example:

- Effectiveness:
  - » Compliance with common quality metrics such as HEDIS, PQA
  - » % denials
  - » % required genomic testing
- Cost [Figure 2]:
  - » Cost per-utilizer-per-month (PUPM)
- Utilization:
  - » Number of prescriptions per-utilizer-per-month (Rx PUPM)
  - » Compliance %, Drug Holiday %, Terminated therapy %
- Risk [Figure 5]:
  - » Efficiency of clinical flags (trended percent of flagged clinical problem to total claims)
  - » Rate of important drug interactions and drug-induced conditions to total claims

These metrics are calculated after the fact and benchmarked to medical practices with similar patient populations (age/gender), severity of illness, disease patterns, and geographic proximity.

Individual physicians and pharmacists (i.e., providers) can calculate their own statistics from quarterly or annual reviews of their own data. This is not an academic exercise as the comparison of individual practice metrics with those published by insurers, PBMs, or CMS can lead to quality improvements, revenue enhancement, as well as defensive maneuvers to support individual practice excellence. Note that it is not always clear what actions are necessary to improve these metrics. Health Plans and PBMs may report results, but specific actions may not be evident. As a result, providers should communicate with Health Plans to determine action plans for improvements and maintain their own records to substantiate progress toward objectives.

Fraud, Waste, Abuse (FWA)

Due to the cost of Specialty medications it is no surprise that insurers, CMS and states are focused on potential fraud, waste and abuse (FWA). FWA analysis is both surveillance for actual fraud and deployment of measures to prevent waste and abuse. Any deviations from averages are a potential target as are providers who display deviations from expected norms. For example providers are reviewed for practices that deviate to a large extent from matched norms:

- Cost
  - » Cost per claim exceeds expected norms
  - » PUPM cost exceeds comparable provider practices
- Fraud or Abuse
  - » Providers with a high percentage of off-label use
  - » Claims exceed QL and/or expected frequency
  - » Claims with zero quantity
  - » Claims with invalid NPI and/or NDC
- Duplicate charges – pharmacy/medical
- # packages paid exceeds comparable locations of service

Arguably, the FWA analyses are a subset of utilization management focused on cost and utilization outliers. Since proving fraud is a lengthy legal process, prevention is the less costly, less resource intensive, and most efficient method for self-correction of outlier performance. Yet prevention is more than identification of high probability providers. It requires behavior modification, and correction of standard or regulatory processes and requirements used by payers that lead to wasteful and abusive practices. Providers should strongly consider re-evaluation of all practices that might fall under any element of FWA and address corrections within their practices. Claims analysis, standardization of data, and the explosion of fraudulent claims submissions are placing a greater emphasis on all providers to be more compliant.

Future Opportunities

The future of utilization management shares a common path for both small molecule and Specialty medications. Considering utilization management as more than decreasing the number of duplicate medications or switching to less costly options, the merging of medical and pharmacy benefits is leading to additional opportunities for competition to control utilization.

Channel competition, whether between medical and pharmacy or between sub-channels, is a market mechanism to control utilization and cost. Pharmacy sub-channel competition between specialty pharmacies, network pharmacies, and PBMs is in its infancy. Pricing competition, access to Specialty pharmaceuticals, provider service, compliance/adherence, and distribution are the current emphases. However, medical sub-channel competition between locations of service (e.g., physician offices, infusion centers, emergency medicine, hospital outpatient, acute care hospitals) is mature and hotly contested. Medical competition targets best-in-class (BIC) and centers of excellence (COE) to provide measurably better care and outcomes at competitive prices. Ultimately, and in short order, it is expected that all channels will be competing over clinical and process outcomes.

The demand for information is creating digital data sharing including performance and cost based pricing "supermarkets." AHRQ historically and the Affordable Care Act both emphasize information sharing between providers – physicians and pharmacists as well as teams of providers in Accountable Care Organizations (ACOs) and medical homes (PCMH) – as well as comparison of clinical quality performance across all channels. The desired result is better care, which means measurable comparative utilization with the beneficiary being lower comparative cost.

The cost of Specialty medications creates a need for cost comparisons, e.g., national pricing (ASP, NADAC, 340b), state Medicaid pricing (AAC, Specialty MAC prices), and PBM/ Health Plan prices. The expansion of the biosimilar market, once naming and coding conventions are decided, will add comparative pricing to these "supermarkets." This additional "transparency" in pricing is expected to apply market controls to Specialty medications similar to managed care market-based models.

Conclusion

If utilization is the great multiplier of cost and resource consumption, then utilization management is the answer to what to do after volume discounts and rebate negotiations to decrease net cost. Specialty medications are the poster child for cost control and utilization management. As a result, the application of utilization practices and the measurement of results will not be ignored.

All providers need to incorporate the integrated approach to utilization management into their practices. They need to keep tables of utilization metrics to document the outcomes of their practices. There is no doubt that insurers, compliance agencies and regulatory bodies will measure, benchmark, and publish results. The transparency of data sharing is, and increasingly will be, standard practice for management of Specialty Medications.

About the Author

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Table 1. Sample Guideline Sources

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Table 2: Benchmark References

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2. Deutche Bank, 2015 Survey. Available at: www.db.com
3. EMD Serono Available at: www.emdserono.com
4. ICER (Institute for Clinical & Economic Review) Available at: www.icer-review.org
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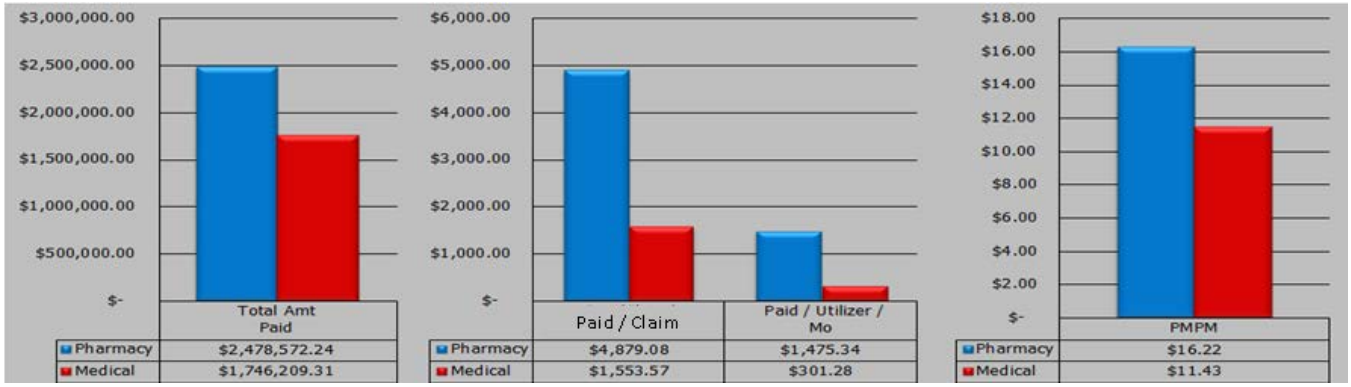
Figure 1. Sample Management Metrics



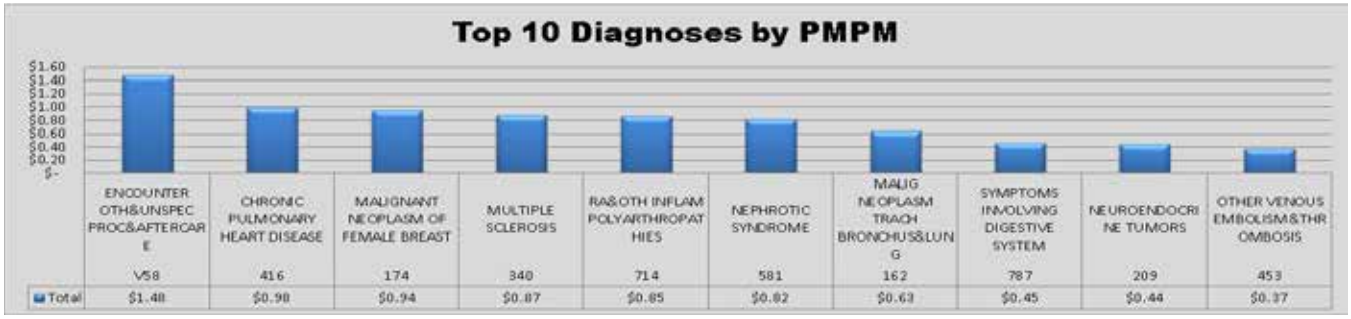
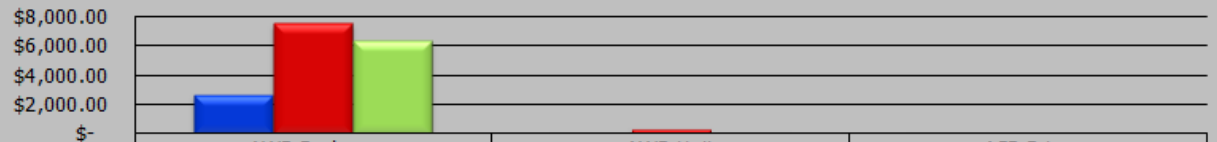


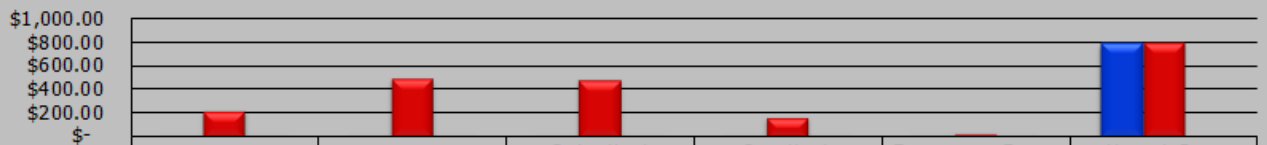
Figure 2. Sample Specialty Pricing Metrics

Benchmark Unit Prices by Pharmacy/Specialty Channel



	AWP Package	AWP Unit	ASP Price
Pharmacy Network	$2,666.41	$2.03	$0.01
Specialty Pharmacy	$7,533.29	$341.19	$6.69
All	$6,364.48	$19.17	$0.34

Benchmark Unit Prices by Medical Channel



	Office	Home	Outpatient Hospital	Inpatient Hospital	Emergency Room Hospital	Urgent Care Facility
AWP Unit	$1.46	$0.07	$2.92	$0.29	$0.35	$791.30
AWP Package	$219.78	$491.33	$486.38	$162.52	$26.78	$791.30
ASP Price	$0.85	$0.06	$1.95	$0.12	$0.08	$-

Number Packages Paid - Medical

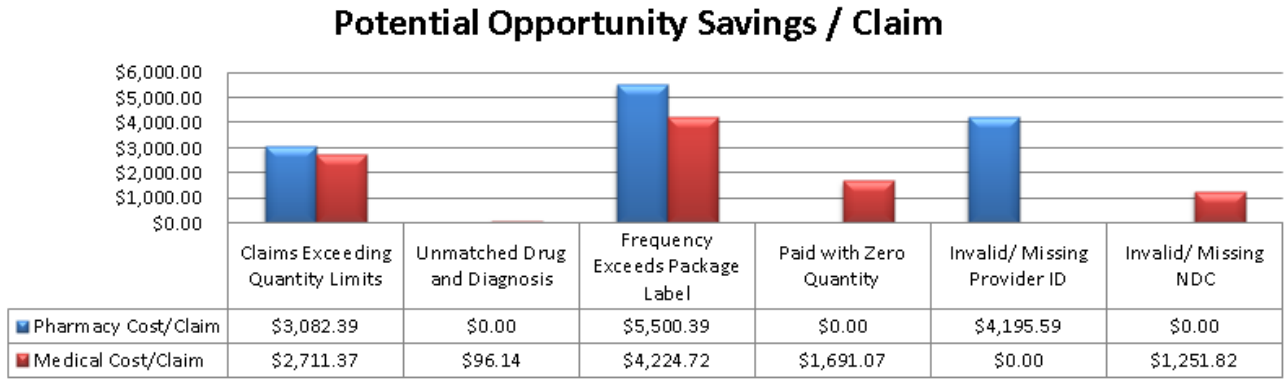
	Office	Home	Outpatient Hospital	Inpatient Hospital	Emergency Room Hospital	Urgent Care Facility
Total	1.3	16.5	2.9	1.9	2.2	0.9

Figure 3. Sample Payment Discounts

AWP Claim Discounts		
Source	*Type / Location*	*Avg Discount*
Rx Claims - All	Brand	13.45%
Rx Claims - All	Generic	26.91%
Pharmacy Network	Brand	13.71%
Pharmacy Network	Generic	24.93%
Specialty Pharmacy	Brand	15.72%
Specialty Pharmacy	Generic	33.13%
Med Claims - All	Brand	42.66%
Med Claims - All	Generic	65.33%
Medical LOS	Emergency Room Hospital	71.35%
Medical LOS	Home	7.00%
Medical LOS	Inpatient Hospital	-14.65%
Medical LOS	Office	53.29%
Medical LOS	Outpatient Hospital	36.94%

Note: Negative discounts indicate AWP +

Figure 4. Common Claims Payment Problems



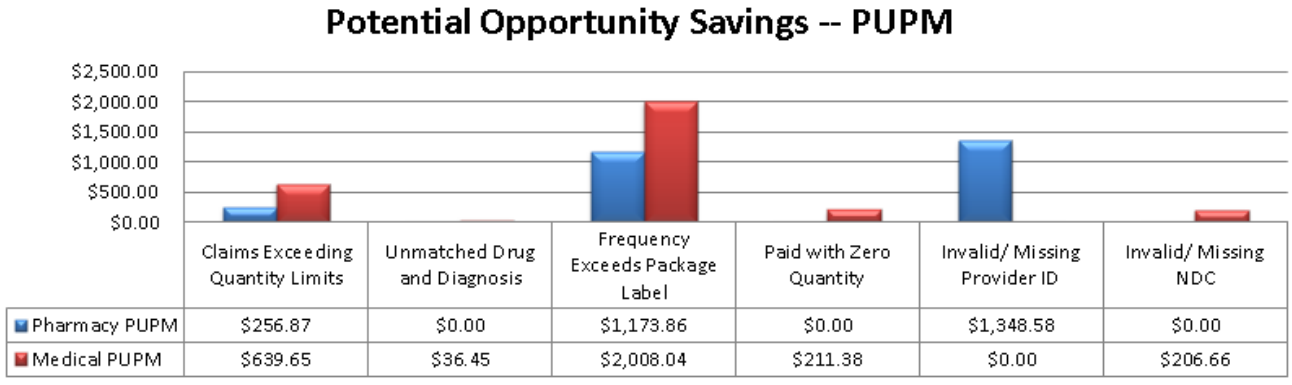


Figure 5. Sample Risk Results From Clinical Assessment

Pharmacy Clinical Assessment		
Category	***Paid per Utilizer per Month***	***PMPM***
Drug Interactions between JCode and Pharmacy Claims	$4,995.79	$0.08
Specialty Drug Adherence and Holiday	$1,482.05	$1.66
Specialty Drug Induced Disease and Adverse Events	$36,768.09	$8.53

Medical Clinical Assessment		
Category	**Paid per Utilizer per Month**	**PMPM**
Drug Interactions between JCode and Pharmacy Claims	$1,840.28	$0.04
Specialty Drug Adherence and Holiday	$1,830.66	$1.44
Specialty Drug Induced Disease and Adverse Events	$11,949.13	$1.74

