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- 1. Why did the State implement a PDL?** House File 619, enacted by the 80th General Assembly, mandated the Iowa Department of Human Services (DHS) establish and implement a PDL. The Medicaid budget was under severe stress and considerable savings were necessary to maintain the integrity and viability of the program.
- 2. What was the general method for constructing the initial PDL?** Each drug was reviewed on its clinical contributions relative to other medications in the same therapeutic category. Published, peer-reviewed clinical trials are the primary source of information used for this review. Placebo controlled, randomized clinical trials were awarded the greatest weight in the consideration process. Data regarding efficacy, effectiveness, adverse effects, and tolerability were analyzed and compared to other drugs within the therapeutic class. From this analysis, the clinical staff determined an agent's therapeutic value relative to the comparator drugs. An economic analysis was performed concurrent with the clinical review. This analysis incorporated Iowa utilization data, the CMS (federally negotiated drug manufacturer) rebates, and any supplemental rebates offered to the state by the drug manufacturers. The fiscal impact of PDL inclusion or exclusion of each medication was then determined. Another level of analysis weighed the relative cost to benefit ratios of accepting supplemental rebates compared to prior

authorizing drugs. The comparable experiences of other states were collected and considered before suggestions were conveyed to the State. After reviewing and discussing these suggestions, the State's drug committee made recommendations to DHS for final determination.

- 3. When did the PDL start?** All providers have been required to submit PAs for non-preferred drugs since January 15, 2005. Exceptions were made for members already established on non-preferred drugs that have been "grandfathered".

- 4. What is the process of reviewing the PDL and adding new products?**

The PDL is reviewed in its entirety annually at the November Pharmaceutical and Therapeutics (P&T) Committee meeting. New drugs, including new generics, are reviewed at each of the three scheduled meetings.

The recommendation for drug status on the PDL is determined by analyzing the clinical trial literature and assessing therapeutic benefit. Clinical benefit is defined as a high level of treatment efficacy, as demonstrated by standard effect size measures (e.g. NNT, Cohen's d). Clinically effective treatments have a low number needed to treat (NNT) as well as a high number needed to harm (NNH). Treatment value is defined as clinical benefit divided by cost. In such a manner, highly effective treatments are of higher value than equally effective though more costly alternatives.

Clinical effectiveness is given primacy in the creation of the PDL with secondary consideration given to cost. Cost is determined by a number of factors including federal and state rebates. Weight is given to well designed, blinded, randomized, adequately powered, active comparator, clinical trials with clearly defined primary endpoints of direct clinical relevance to morbidity and mortality.

Appropriate handling of non-completers and subgroup analyses is similarly assessed. Expression of absolute effect size is most helpful as is comparison to active medications. A proprietary evidence rating scale is used to assess studies on a number of relevant metrics leading to a determination of LOE (level of evidence).

New pharmacologic agents are presented to the Pharmaceutical and Therapeutics Committee (P&T) as written new drug reviews. All recommendations are discussed and voted on by the P&T Committee in open session allowing a transparent dialog of each specific treatment. PDL placement is ultimately recommended by the P&T Committee with input from IME, and finalized by the Department.

- 5. How much has the State saved?** The PDL was implemented in January 2005 and has saved the state nearly \$489 million through SFY15 (state dollars).

- 6. Is a Preferred Drug List (PDL) the same as a formulary?** A formulary is a list of drugs that are available and approved for use by a variety of insurance companies, managed care organizations, hospitals, and governmental entities. Drugs must be prescribed from the formulary, and no exceptions are typically available. In contrast, a Preferred Drug List (PDL) is a component of the Prior Authorization (PA) process. So while all medications on the PDL are available, in order for reimbursement to occur, Iowa Medicaid requires that certain medications must be approved beforehand. This approval is based on previously specified criteria. Medications deemed to be clinically and/or economically superior to other clinically similar drugs are placed on the PDL. Most medications on the PDL can be prescribed and dispensed without prior authorization. Some preferred medications still have dose consolidation considerations and quantity limits that apply.
- 7. Who develops the PA criteria?** The PA criteria are developed jointly by the P&T and the Drug Utilization Review (DUR) Committees. The P&T concentrates on choosing preferred drugs in drug categories that have multiple therapeutic choices available. Access to non-preferred drugs in these categories depends on failure/side effects/contraindications of preferred drugs. The DUR focuses on designing clinical criteria for a variety of drugs that are potentially very expensive, unusual, or subject to abuse. The criteria concerning access to these drugs may involve confirmation of an appropriate diagnosis and/or meeting several drug trials across different drug categories.
- 8. Are new drugs included on the PDL?** New drug entities (including new generics), and new drug product dosage forms of existing drug entities in therapeutic classes of drugs already reviewed by the P&T Committee will be identified weekly from the DHS Medi-Span price update reports, then immediately coded as "Non-preferred-Prior Authorization required." These drugs will be considered non-preferred until presented at the nearest scheduled P&T Committee meeting. If a new medication is considered unique and has been classified as a priority drug by the FDA, the State may indicate that this drug is preferred until the drug is reviewed by the P&T Committee at the nearest scheduled meeting. Supplemental rebate offers on new drugs may be submitted and will be considered, if received at least six weeks prior to the next P&T meeting.
- 9. How are future updates in the PDL communicated to companies and the public?** The PDL is published on the Iowa PDL website at www.iowamedicaidpdl.com. All updates and a variety of related data, reports and assorted drug information are posted and archived here. Prior authorization forms and criteria are located here, as well.
- 10. What is the difference between the PDL (Preferred Drug List) and the RDL (Recommended Drug List)?** Iowa operates two drug lists for the State Medicaid

Program. The first is called the Preferred Drug List and within it all non-preferred drugs are available but subject to prior authorization. The second list is the Recommended Drug List. This group of drugs is subject to clinical prior authorization only if indicated in the comment section. These drug categories include drugs primarily for treatment of human immunodeficiency virus or acquired immune deficiency syndrome and cancer. The P&T Committee classifies RDL drugs as either recommended or non-recommended on the basis of their relative clinical/cost values. The State favors recommended drugs equally with preferred drugs, as the State may collect supplemental rebates from drugs on both lists.

11. Who makes the final decision as to what drugs are included on the PDL?

The Medicaid Director, within the Department of Human Services, has the authority to make these decisions, following the recommendations by the P&T Committee.

12. I cannot find certain drugs listed on the PDL or RDL. What does this mean?

New drug entities, including new generics and new drug product dosage forms of existing drug entities, are typically non-preferred initially and are not added to the PDL until after being reviewed by the P&T Committee for a final recommendation. The PDL and RDL represent the most utilized drugs by Iowa Medicaid members.

13. Will patients be required to switch their medications if they are stabilized on a non-preferred drug?

In many instances the answer is yes. Some medications in certain classes, however, have been "grandfathered". This means that patients already stabilized on a medication that is listed on the PDL as "grandfathered" will not require a PA to continue on that medication.

14. Is there any real difference between preferred and recommended?

Not really. Both signify cost-effective therapeutic choices that save the State money. The State wants to equally encourage use of both preferred and recommended drugs.

15. Is there any real difference between non-preferred and non-recommended?

Yes. Although both choices result in greater expense to the State, only the use of non-preferred drugs is subject to prior authorization at this time.

16. Are there some therapeutic classes that will be excluded from the PDL PA process?

Yes, in general drugs used for the treatment of human immunodeficiency virus or acquired immune deficiency syndrome and cancer are excluded from the PDL PA process which is based on a drug's non-preferred status, however they may be subject to a clinical PA requirement ensuring appropriate use of the medication being requested.

17. Why do some preferred drugs say PA is required? Isn't this the same as being non-preferred? Some PDL drug categories contain PA requirements concerning medical necessity that apply to any drug residing there. Despite this PA condition, some or all of the drugs in the category may be preferred if the basic medical necessity requirements for such a drug is satisfied. For example, in the EPO category, Procrit is preferred among the choices available but first it must be demonstrated that a significant and EPO-responsive anemia exists. The same is true of the growth hormones with Norditropin preferred but only after the necessary medical documentation concerning indications is supplied. The key difference is that being non-preferred within a PDL category generally means that failure on preferred products within the category is the central issue in deciding whether to grant approvals for non-preferred drugs, whereas access to preferred drugs requiring PA means that the core issue is one of confirming the diagnosis and/or medical necessity for a drug in that class.

18. Why are some brand name drugs preferred over generic versions? The cost benefits of generic use are not as black and white as commonly perceived and portrayed in the media, especially for Medicaid programs. State Medicaid programs participate in a federally negotiated rebate program with drug manufacturers. This means they receive a varying percentage of the cost of every drug back from the manufacturer. In some cases, Medicaid drug rebates for brand drugs can exceed 95% of their list price/acquisition cost. This makes Medicaid's net cost for these brands very low, in some cases approaching \$0. While the list price of generic equivalents may be 50% lower than the brand, the rebates for these generics is also lower, usually around 10% of WAC. This dynamic can make the net cost of a generic higher than the net cost of its equivalent brand (sometimes, significantly so). As a result, in cases such as this, the brand is preferred and the generic is non-preferred. Usually, after there have been multiple generics on the market for some time, their acquisition cost goes down. When the net cost of the generic is closer to that of the brand, the state changes the PDL so that the generics are preferred over the brands.

A list of brands preferred over generics is provided (Brand Preferred Over Generic List) and also posted on the website. If and when future generic price caps are implemented, resulting in the generic becoming less expensive, the affected brand and generic will reverse positions in the PDL.

19. Why are certain strengths of some medicines non-preferred? Some drugs have strengths that are non-preferred because they are priced too exorbitantly relative to other strengths. One fluoxetine 40 mg cap cost three times as much as two 20 mg caps. Requiring the use of multiple 20 mg caps will save several hundred thousand dollars annually. Drugs affected by strength restrictions are described in the comments section of the PDL cover page, abbreviated as "COM".

20. Is there a possibility that existing prior authorizations will be removed? Yes. The State will evaluate the advantages and disadvantages of any scenario posed. Removing or restructuring utilization controls will be strongly considered

depending on the relative merits of each unique situation. This means that companies with non-preferred products may submit supplemental rebate offers at any time. If it is advantageous to the State and if there is no conflict with an existing supplemental rebate agreement with another manufacturer, then a non-preferred drug may be designated as preferred.