

Workshop A: Case Studies in PAP Design

CBI 9th Annual Patient Assistance Programs Conference
Nicole Coustier, Principal
March 4, 2008



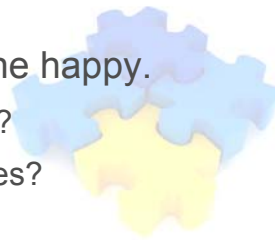
Compelling changes to the PAP environment

- Internet: educational portal and data access
- Medicare Part D
- OIG guidance and restrictions
- Shifts in insurance coverage availability
- Changing clinical guidelines
- Availability of new drugs
- New and different indications



Some thoughts to start out...

- Change is disruptive, and we can always expect change.
 - So what is your plan for keeping up or being ahead of the curve?
- One size doesn't fit all.
 - Do you *really* know what your customers/patients want and need from you?
- You probably won't make everyone happy.
 - What is your ultimate PAP objective?
 - What are your intermediate objectives?



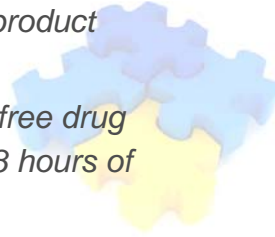
Objective

- To illustrate the various PAP design options available to you
- To give you some tools and considerations for finding the right PAP fit for your product, your customer base, your patient population, and your overall company philosophy



Begin at the beginning

- Define your PAP objectives and strategy
 - Can everyone on your team articulate it?
 - Can everyone in your organization articulate it?
- Examples:
 - *Our PAP objective is to maximize uninsured and underinsured patient access to our product in a timely manner.*
 - *Our PAP strategy is to implement a free drug program that provides drug within 48 hours of application approval.*



What are the options?

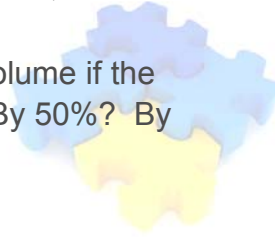
- Dependent upon:
 - Your product (including setting of care)
 - Your customer base and patient population
 - Your overall company philosophy

- Case studies:
 - Large scale retail pharma
 - Office injection
 - Hospital inpatient infusion
 - Replacement or bulk product



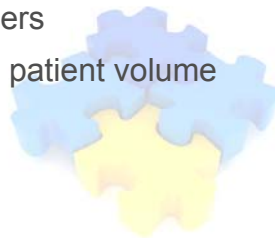
Case Study 1: Large scale retail pharma

- Situation:
 - High volume transactions
 - Patients falling through the cracks – too much income, not enough coverage
- Research:
 - Are patients uninsured, or underinsured, or both? In what percentages?
 - What increase in inquiry and drug volume if the income limit is increased by 25%? By 50%? By 100%?



Case Study 1

- Results:
 - Expand coverage to Part D patients within OIG guidelines
 - Increase FPL % income requirements
- Next steps:
 - Communicate to patients and providers
 - Monitor every 6 months for trends in patient volume and drug distribution



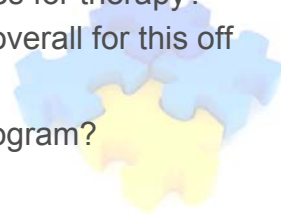
Lessons

- Quantify potential impact of program changes
 - Obtain the right data, depending on your objectives
- Measure the actual impact
 - Not just numbers, but survey users



Case Study 2: Office injection

- Situation:
 - Off label use
 - Low volume PAP utilization – is the program useful to patients and providers?
- Research:
 - What are the current payer guidelines for therapy?
Have there been downward trends overall for this off label indication, or just the PAP?
 - What do providers say about the program?



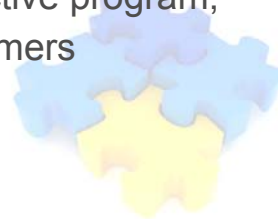
Case Study 2

- Results:
 - Application process was high effort, yet low need
 - Established good coverage under Medicare and private payers over time
 - Discontinued off label PAP in office setting
- Next steps:
 - Communication plan
 - Transition existing patients to other sources



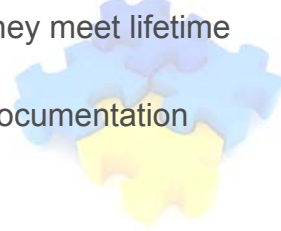
Lessons

- Policy impacts PAP need and utilization
 - Ensure you understand the coverage and reimbursement environment and apply that information to your PAP design
- Understanding when to scale back or increase services will allow for a cost-effective program, and still serve the needs of customers



Case Study 3: Hospital inpatient infusion

- Situation:
 - Intensive therapy, high cost
 - Patients are scheduled in advance
 - Select hospitals provide the service
- Research:
 - What is the potential volume of patients in need? Do patients have coverage? If so, do they meet lifetime maximums?
 - What are the right application and documentation requirements?



Case Study 3

- Results:
 - Must be completely uninsured (refer to other options if underinsured)
 - Get full application and income documents up front
 - Prospectively provide drug (sent from manufacturer directly)
- Next steps:
 - Outsource PAP screening and enrollment to experienced vendor



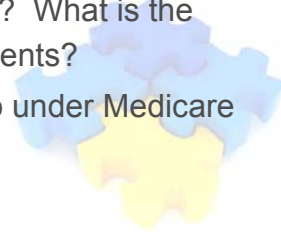
Lessons

- Build relationships with your key customers for PAP uptake, acceptance
- Investigate when it make sense to take in-house versus outsource
 - Screening
 - Enrollment and re-enrollment
 - Drug distribution



Case Study 4: Replacement or bulk product

- Situation:
 - Injection used in non-emergent situations
 - Most commonly hospital outpatient or physician office settings, traditional buy-and-bill model
- Research:
 - How do providers stock this product? What is the volume of utilization for indigent patients?
 - What is the reimbursement scenario under Medicare and private payers?



Case Study 4

- Results:
 - Simplified application process
 - Send drug in a timely manner, but not an urgent situation
- Next steps:
 - Determine date of service limitations (if any)
 - Determine product volume limitations (if any)



Lessons

- Know the trade-offs in your PAP design
 - Replacement programs make it harder for providers to collect income documents
 - Limitations may adversely impact some provider types
- Set users' expectations
 - When drug will arrive, what application requirements are





Thank you!

Nicole Coustier
415-835-0190 ext 120
Nicole.Coustier@QuorumConsulting.com

