



## The Zitter Group Managed Market Strategy Checklist<sup>®</sup>

Managed markets influence over 75% of prescriptions written. Increasingly, this influence extends to biologics and injectables as well as traditional small molecules, devices, and diagnostics. As costs continue to rise, managed market customers will play a critical role in determining the success or failure of drugs and other medical products. Medicare's prescription drug benefit has only increased the influence of commercial payers. The Zitter Group has developed this Checklist<sup>®</sup> as a guide for centralizing information relating to your managed market strategy. It is our hope that this Checklist<sup>®</sup> will help you optimize your brand's access to the payer market.

### Part I: Sales Projections and General Overview

|        | Total Sales For Product (\$M) | MC Sales for Product (\$M) | %MC |
|--------|-------------------------------|----------------------------|-----|
| Year 1 |                               |                            |     |
| Year 2 |                               |                            |     |
| Year 3 |                               |                            |     |
| Year 4 |                               |                            |     |
| Year 5 |                               |                            |     |

Apart from the financial figures above, how would you characterize the likely influence of payers on the success of your product?

Which indication(s) will drive the bulk of the product's sales? How will the timing of approval for new indications affect forecasted sales?

Total U.S. market for therapeutic class, current year (\$M):

Product's market share, current year (%) or first year projection for pre-launch products:

Total U.S. market for disease, all relevant product categories, current year (\$M):

Which products represent your primary competition?

| Product | Manufacturer | Years on Market | Share |
|---------|--------------|-----------------|-------|
|         |              |                 |       |
|         |              |                 |       |
|         |              |                 |       |
|         |              |                 |       |
|         |              |                 |       |

What are your principal managed market goals for the product? (select all that apply)

- a) Maximum coverage
- b) Favorable formulary position
- c) Advantageous co-pay level
- d) Formulary access
- e) Equivalent formulary position v. competitors
- f) Favorable reimbursement rate
- g) Reasonable/light Prior Authorization restrictions
- h) Acceptance of new indication(s)
- i) Visibility
- j) Collaboration on pull-through
- k) Sales growth
- l) Preparation for new entrant
- m) Preparation for patent loss by market incumbent
- n) Other

## Part II: Strategic Planning, Market Research, and Analysis

### 1. Product Differentiation

How does or will the message you use with your business customers (i.e. payers) differ from the one for professional customers (i.e. physicians and other health professionals)?

Which product attributes or associated use attributes represent the greatest sources of value for your managed care customers? (select all that apply)

- a) Improved efficacy v. competing treatment
- b) Improved safety v. competing treatment
- c) More attractive price (ASP/WAC/AMP[Average Manufacturer's Price]) v. competing treatment
- d) More attractive net price v. competing treatment (rebating/discounting)
- e) Advantageous dosing frequency or schedule
- f) Mode of administration advantage v. competing treatment
- g) Unique or innovative mechanism of action
- h) Reimbursement support
- i) Favorable HECON data v. other treatments
- j) Breadth of indications
- k) Ease of prescribing/use for physician
- l) Value-added programming
- m) Other

Which product attributes or associated use attributes represent the greatest sources of weakness for your product? (select all that apply)

- a) Efficacy
- b) Safety
- c) Price (ASP/WAC/AMP)
- d) Net price (rebating/discounting)
- e) Dosing frequency or schedule
- f) Mode of administration
- g) Mechanism of action
- h) Lack of reimbursement support
- i) Opportunity for off-label use
- j) HECON data
- k) Difficulty of prescribing/use for physician
- l) Lack of value-added programming
- m) Other

Which disease/therapeutic issues or problems (listed below) in your product's therapeutic area might represent opportunities for you to assist your managed market customers in mutually beneficial ways? (Check all that apply)

- Under-diagnosis/misdiagnosis
- Existing national treatment guidelines
- Compelling scientific literature favoring your product or therapeutic category
- HEDIS/NCQA/ P4P/JCAHO requirements
- Lack of physician adherence to guidelines/protocols
- Lack of patient awareness of key issues
- Lack of patient compliance with prescribed therapy
- Lack of payer/purchaser appreciation of cost of condition/disease
- Generally low level of understanding of condition pathophysiology, progression, and related issues
- Under leveraged economic advantages that could be realized through co-promotion with MCOs
- Successful disease management programs that have resulted in increased use of your class of product

Have you conducted primary research to evaluate how customers value these (and other) attributes?

## 2. Market research and analysis

What primary market research have you conducted with managed care decision-makers, as opposed to physicians? (select all that apply)

- a) Evaluation of product attributes - Quantitative/Qualitative
- b) Assessment of preferences Quantitative (conjoint/discrete choice analysis)/Qualitative
- c) Brand identity audit and attribute deficiency analysis
- d) Pricing evaluation
- e) Market segmentation and account prioritization
- f) Advisory boards
- g) Message Testing/Value Propositions

Key findings from primary market research

Key findings from advisory boards:

Other input:

Based on research and/or advisory boards conducted, do your business customers understand and acknowledge your product's points of differentiation?

What are the primary drivers of product performance? Which variables correlate with observed changes in utilization?

**3. Managed Market Sector Strategies:** How, if at all, does your strategy vary for each of the following customer groups or segments? Which of these sectors represents a critical determinant of your product's success? Why or why not? Which sectors represent the biggest threats? The biggest opportunities?

Health Plans (HMOs, PPOs, POS, etc.):

PBMs:

Medicare (distinguish Part B, Part D, and Medicare Advantage Plans):

Medicaid:

Hospitals:

Veteran's Administration:

DoD:

Specialty Pharmacy Providers:

Long-Term Care Institutions:

Physician Group Practices:

Employers:

Others:

#### 4. Account Segmentation and Resource Allocation Prioritization

Which accounts represent your strategic priorities for the coming year?

Which accounts represent your key contracting targets for the coming year? :

What is the basis for this prioritization or assignment of strategic importance? [select all that apply]

- a) Account size
- b) Account share of local/regional markets
- c) Market composition
- d) Brand market share within account
- e) Level of "control"
  - which variables are used to assess control?
- f) Sales volume within account
- g) Product formulary status
  - 1. absolute
  - 2. relative
- h) Status of other company products
- i) Relationships
- j) Other (please identify)

Does your prioritization or segmentation approach capture differences in how accounts use your product, or assign value to its key attributes?

How are different payer-directed resources prioritized and allocated?

What is the basis for determining whether, where, and for how much to contract?

How are pull-through programs (if any) allocated to ensure the likelihood of greatest return?

How are other programs prioritized and allocated?

How are MSLs and other field-based resources deployed to provide the greatest impact?

## 5. Positioning

How will you position your product with each of these audiences or segments?

| Audience/Segment                | Key positioning elements/message |
|---------------------------------|----------------------------------|
| Medical Directors/<br>CMOs      |                                  |
| Pharmacy Directors              |                                  |
| Other MCO<br>audiences          |                                  |
| Priority Accounts               |                                  |
| Other accounts                  |                                  |
| Health Plans                    |                                  |
| PBMs                            |                                  |
| Specialty Pharmacy<br>Providers |                                  |
| Group Practices                 |                                  |
| Employers                       |                                  |
| Long-term care<br>organizations |                                  |
| Veterans<br>Administration      |                                  |
| State Medicaid<br>Programs      |                                  |
| Medicare                        |                                  |

How will you position your product against each of these competitors?

| Competitor   | Key positioning elements/message |
|--|----------------------------------|
| Internal competitors<br>(products marketed<br>by your company<br>targeting the same<br>disease(s)) |                                  |
| Other drugs within<br>the class  |                                  |
| Other drugs outside<br>the class, within the<br>category   |                                  |
| Non-<br>pharmaceutical<br>therapies  |                                  |

## 6. Economic Positioning Message and Strategy

Summarize your brand's economic rationale? (select all that apply):

- a) Greater cost-effectiveness v. standard treatment
- b) Medical cost offsets or reduced downstream costs
- c) Reduction of resource utilization
- d) Enhanced efficacy or slowed progression
- e) Enhanced patient productivity
- f) Reduced disability (including DALY analysis)
- g) Enhanced QOL (including QALY analysis)
- h) Other

How would you summarize your product's economic rationale?

What are the key studies and/or models that support your economic message or rationale?

What are the major economic barriers your product faces in accomplishing your sales goals?

## 7. Reimbursement and Benefit Classification (for injectables and biologics)

Does product reimbursement represent a significant objective and/or challenge for your product?

Does patient access to the product and/or reimbursement vary with benefit classification (e.g. medical v. pharmacy)?

What % of accounts currently reimburse or you anticipate reimbursing the product? What % of accounts represents your goal for the coming year?

What role do/will specialty pharmacy vendors play in access and/or reimbursement decisions?

Do managed care accounts seek to increase patient self-administration of injectable and/or biologic products? How does this affect your product?

To what extent does/will prior authorization represent a challenge for your product?

To what extent will increased patient cost-sharing for your category disadvantage your product relative to its direct competitors?

What percentage of your accounts anticipate moving to – or already have moved to – ASP-based reimbursement?

Are there any significant differences between competing products that will affect Medicare's coverage and/or maintenance of them (e.g. Part B v. Part D, assessment fees, etc.)?

## **8. Payer Contracting**

Have you developed a strategy to contract? If so, how do you plan to measure success?

Does your contract provide for incremental sales, prevent loss of sales or have little or no measurable effect?

### Access Contracts

How do you plan to compete with Access Contracts?

How will you measure the Access Contract success?

### Step Edits/Therapy

What strategies will you employ to grow a brand that is subject to a Step Edit Generic Failure (SEGF)?

Will you consider growth in net sales a victory, even though you have paid through a Step Edit?

Will your strategies involve paying a rebate in Tier 3? If so, how will you measure success?

- a) Will you pay a rebate for a Tier 3 listing with SEGF criteria? Why / Why Not?
- b) Will you gain enough incremental net sales in Tier 3 by contracting a brand position against a similar brand?

### Competitive Launch Contracting

What strategic actions are you taking for a competitive product launch?

## Part III: Planned Marketing Tactics

### 1. Communication Tactics

What live (on-site, Web- or phone-based) MC customer communication programs are planned for the coming year to deliver the key managed care and economic messages?

| Program | Timing | Message | Purpose* |
|---------|--------|---------|----------|
| 1.      |        |         |          |
| 2.      |        |         |          |
| 3.      |        |         |          |
| 4.      |        |         |          |
| 5.      |        |         |          |

(\* for Purpose, please select from the following: advisory, promotional, educational, or other)

Are you satisfied with your current advisory boards? Why or why not?

What is the brand's managed care/economic publication schedule for the year?

| Publication | Focus of Article | Written By |
|-------------|------------------|------------|
| 1.          |                  |            |
| 2.          |                  |            |
| 3.          |                  |            |
| 4.          |                  |            |

What formulary kit tools (including the AMCP Dossier) are used or planned to communicate your message?

- 1.
- 2.
- 3.

What electronic/new media channels (e.g. Web site, Internet newsletter, e-training) are in use or planned?

- 1.
- 2.
- 3.

What other communication tactics will support your managed market strategy?

- 1.
- 2.
- 3.
- 4.
- 5.

### 2. Pull-Through

What plans are there in the coming year to drive product pull-through in managed accounts?

How do the product's direct-to-consumer activities link with the managed market strategy?

What co-promotions are planned with major accounts?

Which electronic pull-through strategies are being used or planned?

### **3. Value-Added Programs**

What value-added programs do you or will you offer to key managed market accounts?

| Program | Objectives |
|---------|------------|
|---------|------------|

1.

2.

3.

### **4. Training**

What internal training resources/programs support or will be developed to support your product:  
For Managed Care Marketing Managers?

For Field Representatives?

For Account Managers?

For Medical Science Liaisons/Medical Information Scientists/Other Field-Based Resources?

### **5. Linkages With Internal Departments**

How are your brand team's managed market efforts linked with those of:

a. Customer/Health Systems Marketing?

b. Health Economics/Outcomes Research/Disease Management?

c. Account Management?

d. Field Sales?

e. Government Affairs?

f. Other?

**6. Resources**

What is the budget that has been allocated to accomplish your goals in the coming year?

How will you justify requests for additional funding for payer markets? What metrics will be used?

How will your team integrate into next year's planning cycle to earmark programs and funding? Timing?

**Part IV: Summary**

Based on the questions and answers above, what are your product's principal strengths in managed markets? Its principal weaknesses? What are the product's primary opportunities with managed care customers? What are the principal threats?

|                      |                   |
|----------------------|-------------------|
| <b>Strengths</b>     | <b>Weaknesses</b> |
| <b>Opportunities</b> | <b>Threats</b>    |

## Part V: Appendix

### Summarized Research Considerations for Managed Markets

| Area of Focus                                    | Questions and Applications   |
|--|--|
| <b>Pricing</b>                                   | <ul style="list-style-type: none"> <li>How much value do payers assign to key product attributes?</li> <li>What is the optimal combination of attributes in order to sustain my price position?</li> </ul>               |
| <b>Utilization management</b>                    | <ul style="list-style-type: none"> <li>How do payers currently manage utilization in this category?</li> <li>What systems/tools/resources can be deployed to help or hurt my product?</li> </ul>                         |
| <b>Preferences and decision-making</b>           | <ul style="list-style-type: none"> <li>To which issues or attributes do decision-makers assign the greatest importance?</li> <li>How do decision-makers trade off different attributes against one another?</li> </ul>   |
| <b>Competitive intelligence</b>                  | <ul style="list-style-type: none"> <li>What has my competitor been saying about my product?</li> <li>What have decision-makers been told about my competitor's new product?</li> </ul>                                   |
| <b>Message testing</b>                           | <ul style="list-style-type: none"> <li>Which messages resonate most powerfully with payers in the current context?</li> <li>How should my message evolve as the market shifts due to generics or competition?</li> </ul> |
| <b>Market sizing and development</b>             | <ul style="list-style-type: none"> <li>Which indication(s) should we pursue for commercialization?</li> <li>What percentage of revenues will come from commercial payers?</li> </ul>                                     |
| <b>Knowledge, Attitudes, and Practices (KAP)</b> | <ul style="list-style-type: none"> <li>How is the condition (pathophysiology, treatment algorithms, etc.) currently managed?</li> <li>How do payers feel about current specialty distribution models?</li> </ul>         |
| <b>Market modeling and segmentation</b>          | <ul style="list-style-type: none"> <li>Where should we put our resources?</li> <li>Which accounts represent contracting and/or pull-through priorities?</li> </ul>   |

### Key Payer Related Questions Across the Product Lifecycle

| Lifecycle Stage                                   | Questions  |
|---|--|
| <b>Early Development (Phase I and II)</b>         | <ul style="list-style-type: none"> <li>Which compounds, proteins, devices and/or indications represent the best long-term revenue generations prospects?</li> <li>What is the value of different delivery systems and routes of administration?</li> <li>What are potential product-based barriers (e.g. complexity of reconstitution, side effects, etc.)?</li> <li>What are the current measurement systems, endpoints and expectations?</li> <li>What is the size of the market for different indications?</li> </ul> |
| <b>Pre-launch (Phase II and III)</b>              | <ul style="list-style-type: none"> <li>How is the condition managed?</li> <li>What are the competing therapies, metrics and outcomes expectations?</li> <li>What are the current standards of care?</li> <li>What is the satisfaction with current therapies or treatment options?</li> <li>What share of the market is realistic?</li> <li>Do revenue expectations justify continued development costs?</li> </ul>  |
| <b>Peri-launch (Late III – early post launch)</b> | <ul style="list-style-type: none"> <li>Which customers will drive financial performance?</li> <li>Which product attributes will resonate most with payers?</li> <li>What are the barriers that must be overcome in order to drive uptake?</li> <li>What is the value proposition and product position that will be delivered to customers in targeted segments?</li> </ul>   |
| <b>Revenue Maximization and Maturation</b>        | <ul style="list-style-type: none"> <li>How can we differentiate our product against new entrants and new technologies?</li> <li>How do new entrants threaten our value proposition?</li> <li>Which accounts must we defend and at what level should we invest in defense?</li> <li>Which contracting strategies and deal structures will be most effective in protecting business?</li> <li>How will distributor consolidation affect my margins?</li> </ul>   |

|                                   |   |
|-----------------------------------|---|
| <b>Product Harvest or<br/>LOE</b> | <ul style="list-style-type: none"><li>▪ How can we balance resource investment with return?</li><li>▪ Which accounts or territories represent the best opportunities to continue to harvest revenue?</li><li>▪ Is there a shift in the priority of accounts due to harvest?</li><li>▪ How significant are potential threats to my margins or revenues?</li><li>▪ What options are available besides contracts and/or price reductions?</li><li>▪ How can we maximize the remaining equity in our brand identity?</li><li>▪ How will market dynamics evolve during the remaining brand life?</li></ul> |
|-----------------------------------|---|