



Linkage – or Lack of Linkage -
between Value, Appropriateness
and Payment Policy for Specialty
Pharmaceuticals

Policy Options and the
Challenges they Present

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[Specialty Pharmaceuticals]

- Value:
 - health benefit per dollar expended
 - “once a *potentially lifesaving* therapy is developed, it is untenable for payors or society to limit access” – how big is the potential, and how does “society” weigh in re limiting access vs. limiting price

[Specialty Pharmaceuticals]

- Appropriateness
 - Clinician decision: right drug, right clinical condition, based on patient need/characteristics; safety, effectiveness and relative cost effectiveness when more than one option available
 - Patient decision: adherence: dosing, duration, directions

[Specialty Pharmaceuticals]

■ Payment Policy

- To date, all brand drugs
- Formulary/non-formulary in commercial business; Medicare Part D – private plans administer, but with many more restrictions on use of formulary to manage utilization and appropriateness
- Tiering – problematic issue of co-insurance for these drugs – price, not psychology of payment, a barrier to access and appropriate use

Potential Policy Solutions/Challenges

■ Value:

- To the individual, and to ? “society”, ? others in the risk pool- and who decides?
- Do we accept, without debate, the current approach to setting prices, and the argument, without push back, that any effort to limit prices will stifle or extinguish innovation
- What are models for partnership between payors and manufacturers that keep price in the mix as a subject for discussion

Potential Policy Solutions/Challenges

- Appropriateness – better information
 - Coverage with evidence development, enabling surveillance (safety) and comparison with existing therapies
 - Comparative Effectiveness Research: recharter FDA, or establish FDA approval as beginning of approval process, not the end
 - More robust pre-release safety data (and adequate FDA funding for safety review), rather than relying on post-release surveillance

Potential Policy Solutions/Challenges

■ Appropriateness

- From Risk-MAPS to REM's - putting safety surveillance in hands of Specialty Pharmacies (SP's), not FDA, and risk in the gen'l population of users; "safety trials" without safeguards of clinical trials, e.g. IRB
- Transparency of findings by SP's, compared to FDA (e.g. Tysabri TOUCH trial)
- Monopoly supplier – issue of restricting access to product through supply chain (SP)

Potential Policy Solutions/Challenges

- Electronic Health Records with total capture of injected, infused and oral meds, queryable by patient, prescriber for large observational and nested-case control studies
- Eliminate “buy and bill”, incentives to use more drug, on more patients, more often
- Biomarker outcome studies – do pharmacogenomic applications and biomarker tools impact clinical outcomes?

Potential Policy Solutions/Challenges

■ Payment Policy

- Biogeneric regulatory framework, with reasonable and not excessive exclusivity (which will limit innovation); eliminate mechanisms for delaying competitor products coming to market
- “Value-based” pricing – based on some consensus indicator of value, e.g. QALY
- “Evidence-based” pricing – release price set in relation to *strength of evidence* of benefit or “relative or incremental” benefit –

Potential Policy Solutions and Challenges

- Reference pricing – outside the US
- Co-insurance : extremely problematic with very expensive, non-discretionary drugs
- Drug licenses (Goldman, HA Jan/Feb 2008) – two-part pricing; addresses the psychology of co-pays as impediment to adherence, not the economic impact of the monthly co-insurance on the absolute affordability of the annual co-insurance for the patient