



Specialty Drugs, Demand for Demonstrated Value and Solutions

**Ventegra**

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## Novartis says \$4M price is reasonable for SMA gene therapy

[Phil Taylor](#)  
November 6, 2018



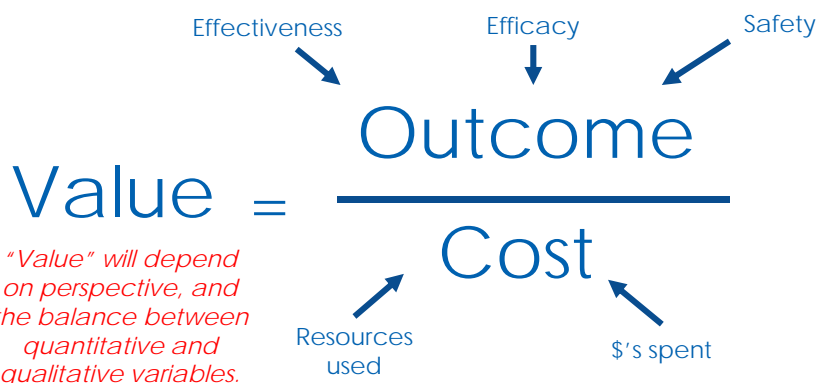
## COST OF SPECIALTY IS NOT 100% REVENUE TO PHARMACEUTICAL INDUSTRY

	DRUG X	INDUSTRY TYPE
AWP	\$5,000	
WAC	\$4,167	
Wholesaler Fee	(\$208)	Oligopoly
Specialty Rx (PBM) Fee	(\$250)	Oligopoly
PBM Fees:		Oligopoly
- Data	(\$140)	
- Development	(\$140)	
- Admin	(\$140)	
- Rebate	(\$417)	
Government Subsidy	(\$1,250)	Monopoly
Net to Pharma	\$1,622	Competitive



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## Payers of Healthcare Are Demanding Value



How do we measure it and once we know what it is, how do we ensure we are only paying for good value?



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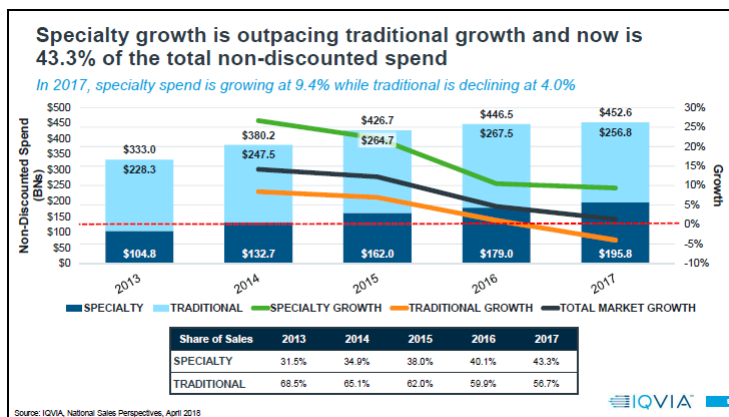
## Specialty, Biosimilar, and Orphan Drugs As Defined by Ventegra

- Specialty Drug
  - *High cost impact*
    - \$1,000 + per month or per dose or \$6000+ per year
  - *Complex/chronic medical conditions*
  - *Limited to small patient populations*
    - Orphan drugs
      - Treatment, diagnosis, or prevention of a rare disease. Rare disease affects < than 200,000 people in the United States
  - *Limited distribution*
    - Special shipping, handling, or storage conditions
  - *Patient education and coordination of care (services, supplies, or devices)*
  - *Patient compliance and/or safety monitoring*



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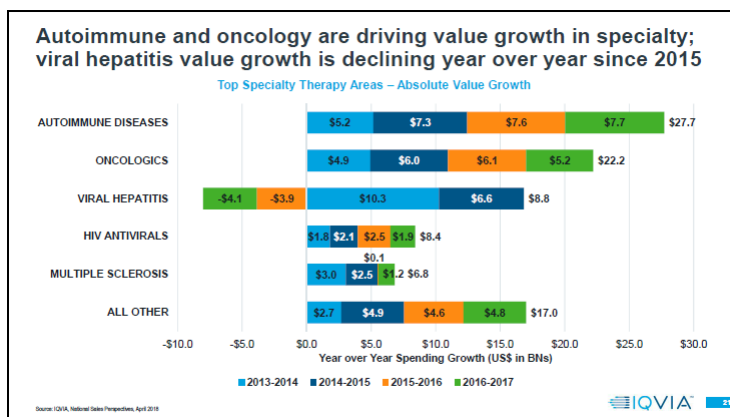
## Specialty/Orphan Drug Market Trends: The Issue at Hand



- Specialty Rx represents 43% of total drug
- Specialty Rx growth at 9.4% vs traditional declining to 4%



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- Autoimmune Diseases and Oncology driving growth in specialty

2017-2018 Pharmaceutical Marketplace Trends: Douglas Long, V.P. Industry Relations, IQVIA. Market Trends and Pricing



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## Orphan Drugs: Current


### Accelerating and changing Orphan Drug landscape

- # of regulatory submissions at an all-time high
- World wide sales reached \$100 billion in 2015
  - *Expected to double by 2022 and represent 1/5 of total prescriptions drug sales*
- Time of increased promise for patients
- Growing sense of concern regarding budget
  - *Not sustainable*
- Much debate between payers, industry, providers and patients regarding orphan drug health coverage with no consensus



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Sample of High Cost Specialty/Orphan Drugs Evaluated to have Insufficient/Marginal Outcome Evaluations				
Drug Name approval	Indication	Reviewed	HST Outcome	Cost
deflazacort (Emflaza) 2/17 PTC Therapeutics	Corticosteroid for Duchenne Muscular Dystrophy	Oregon Health Authority	High Cost/Marginal benefit. Refer to HERC for funding placement	\$65,000/year
telotristat (Xermelo) 2/17 Lexicon	Carcinoid Syndrome diarrhea	WellMark	NMN for all indications, including tx of carcinoid syndrome diarrhea due to insufficient evidence to demonstrate clinical efficacy	\$72,000/year
deutetrabenazine (Austedo) 4/17 Teva	Huntington's Disease (4/17) Tardive Dyskinesia (9/17)		Approved through 505(b)(2) pathway with tetrabenazine as reference listed drug. Can utilize tetrabenazine	\$124,168/year
cerliponase alfa (Brinvera) 4/17 Biomarin	Batten Disease	NICE	Rejected citing lack of long-term evidence about its effectiveness in stabilizing disease and preventing death. Does not appear to provide value for money within the context of a highly specialized service, and cannot be recommended for use in the NHS.	\$702,000/yr.
Nusinersen (Spinraza) 12/23/16 Biogen	Spinal muscular atrophy in pediatric and adult patients	TBD	ICER scheduled to review 3/7/2019. Comparative clinical effectiveness of AVXS-101 (Novartis) and Spinraza	\$750,000 1 <sup>st</sup> yr., \$375,000 subsequent

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## Challenges to Assessing "Value" of Orphan Drugs

Lack of standard patient-focused outcome measures

Lack of surrogate measures for some genetic conditions

Lack of standardization of usual supportive care

Long-term safety and durability of effect in novel MOA (i.e. gene therapy)

Quality of life difficult to evaluate in infants/children

Lead to proposed approaches to cost-effectiveness analysis of orphan drugs

- Modified cost-effectiveness with modified value standards
  - *Use different cost-analysis thresholds*
  - *Specific variations to the QALY (i.e. weighted QALY)*
  - *Role of contextual factors*

[https://icer-review.org/wp-content/uploads/2017/02/ICER\\_Assessing-the-Value-of-Drugs-for-Rare-Conditions\\_051017.pdf](https://icer-review.org/wp-content/uploads/2017/02/ICER_Assessing-the-Value-of-Drugs-for-Rare-Conditions_051017.pdf)



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## MANAGED CARE SOLUTIONS

- Benefit Design (Patient Cost Share, Caps, Deductibles, Exclusions, etc.)
- Formulary (Closed, Edits (Step, age, etc.))
- Utilization Management (Rx \$ triggers, PA's, Therapeutic Interchange, etc.)
- Systems/Processing – New Processes



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## Managed Care Control Levers

- Rigorous PA guidelines with possible peer review
- Exclusive specialty pharmacy provider
- Maximize Pharma contracting
- Recommended formulary exclusions using defined guidance (add to existing PA guidelines if available)
  - Drugs exceeding ICER's value-based threshold
    - *\$150,000 or other determined amount*
  - Clinical guidelines
  - Ventegra Specialty Inclusion Program (SIP)
    - *Essential (life saving)*
    - *Non-Essential (life enhancing with positive ROI)*
    - *Not Covered*



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## What We're Seeing in the Market

- High Cost Patients being “lasered” Out of Coverage by Reinsurers (Payer Still at Risk)
- Exclude Spouses from Medical and Rx Benefits
- Generic Only Coverage – Medical and Rx
- Exclude Specialty - Medical and Rx



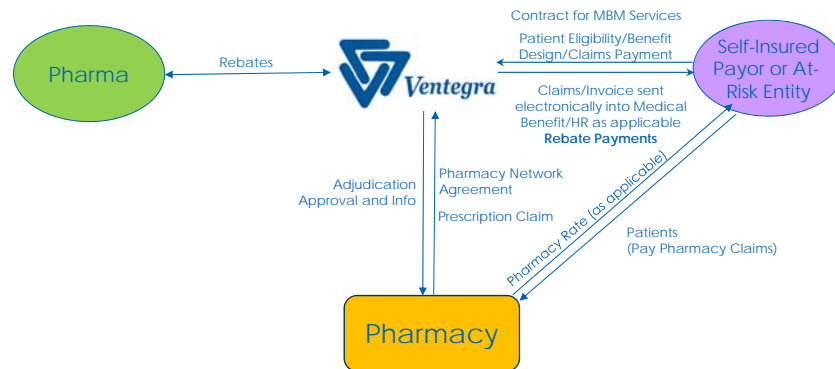
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## TECHNOLOGY AND NEW PROCESSES

- Ventegra is an MBM that specializes in administering benefits for drugs regardless of benefit designation.
  - PSA = Pharmacy Services Administration for pharmacy benefit
  - MSA = Medical Services Administration for medical benefit
- MBM allows Pharma to provide discounts on drugs in a consistent manner, regardless of whether the drug is in the medical or pharmacy benefit.
- MSA would allow electronic claims adjudication for electronic pedigree compliance, administrative simplification, efficiency, transparency and data granularity.
- MSA would allow Payors to administer a consistent formulary regardless of benefit design (e.g., medical vs pharmacy), and control utilization.
- MSA eliminates potential conflicts-of-interest inherent within PBM specialty model through introduction of an independent third party (Ventegra).

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## Medical Services Administration (MSA)



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## Advantages of MSA for Payor

- Electronic claims information into Payor would provide for more data granularity and transparency for population health programs.
  - Can be simple invoice with claim details submitted into HR or Finance Department
- Ventegra IS/IT systems would enable TURNKEY, non-disruptive administration of innovative benefit designs and utilization management (formulary, electronic step edits) for drugs within the medical benefit.
  - Would allow consistent benefit administration of drugs in both medical and pharmacy benefit since capabilities for payor would now be equivalent.
- Ventegra systems could administer accurate “up front” discounting by Pharma (more savings realized by client).

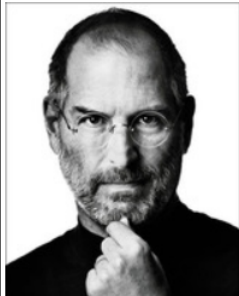


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*“Great Things in Business are Never Done by One Person,  
They’re Done by a Team of People.”*

*Steve Jobs (“60 Minutes,” 2003)*



“My model for business is The Beatles. They were four guys who kept each other kind of negative tendencies in check. They balanced each other and the total was greater than the sum of the parts. That’s how I see business: great things in business are never done by one person, they’re done by a team of people.”

– Steve Jobs

tags: business, team, work



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Questions?



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