THE FUTURE OF MARKET ACCESS:

THREE DISRUPTORS & THREE ENABLERS

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Ipsos has identified a series of "gamechangers" or potentially disruptive healthcare trends with associated market access challenges.

These include:

- Real-time disease management
- Precision medicine
- Innovative healthcare funding and payment
- Greater patient responsibility for health

In parallel, ISPOR has published its 2019 Top 10 HEOR Trends:

1. Drug spending and pricing
2. Going beyond universal health coverage
3. Real-world evidence
4. Aging population
5. Price transparency: Not just about drugs
6. "Big data" continue to make noise
7. Value assessment frameworks
8. Healthcare decision making in low-income countries
9. Personalized/precision medicine
10. Unhealthy behaviors

This white paper takes both complementary sets of trends and analyzes the insights to identify:

- Three disruptors and
- Three enablers that would facilitate companies' ability to successfully deliver access and value in the future.

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Disruptor #1: Evolution of science & technology

Science and technology will be the biggest disruptor of the healthcare landscape of the future, with the convergence of digital and genomic technologies enhancing the efficiency of healthcare delivery and making disease management more personalized and precise.

The linking of patient-level, real-world/real-time data (sourced through digital monitoring, interventional disease management and predictive analytics) – together with precision medicine/personalized healthcare – offers the promise of improving economic, clinical and humanistic outcomes (ECHO).

Technology is, however, evolving faster than the regulatory, behavioural, healthcare funding and Health Technology Assessment (HTA) systems that are required for successful implementation.

For digital and genomic technologies to deliver on the promise, changes will be required in:

- Regulatory and HTA assessment systems
- The roles of the physician and data in disease management
- Payment systems and the pricing of healthcare
- Payer and patient willingness to pay

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Disruptor #2: Evolution of assessment systems & evidence requirements

There will be a shift in focus from the assessment of a drug, diagonistic or device in isolation to a more holistic assessment of the value of healthcare – disease prevention and disease management.

Regulatory and Health Technology Assessments will increasingly embrace data and evidence beyond traditional randomised controlled trials (RCTs).

New types of data may include:

- Real-time data: Data collected through digital health technologies, including apps and wearables
- Primary care databases
- Secondary care databases, e.g. Hospital Episode Statistics (HES)
- Audits of clinical practice, and registries of the use of medicines, devices and other technologies
- Surveillance and monitoring data, e.g. drug safety monitoring data
- Datasets released by public health and social care authorities
- Data that represent the views and experiences of people using services, whether captured formally, e.g. via surveys or informally, e.g. via online discussion forums and social media or patient experience sites such as healthtalk.org
- Data collected by patient organisations

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Disruptor #2: Evolution of assessment systems & evidence requirements

Assessment frameworks will expand to incorporate multiple different areas of value:

Areas that are increasingly likely to be incorporated in HTA decision-making in the future include:

1. Reduction in uncertainty – additional value from knowing a treatment is more likely to work
2. Value of hope – willingness to accept greater risk given a chance or a better health outcomes cure
3. Real option value – the value of benefiting from future technologies due to life extension
4. Insurance value – psychic value provided by invention of an innovative medical products and by the accompanying financial risk protection afforded by a new targeted digitally informed treatment
5. Scientific spillovers – value due to our innovations and improvements in disease management that become possible once a new technology has been proven to work and adopted
6. Cost savings outside the health system

Ref: Adapted from: The value of knowing and Knowing the value: Improving the Health Technology Assessment of Complementary Diagnostics. OHE-EPEMED, July 2016

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Disruptor #3: Inadequacy of funding & payment systems

Pressured by aging populations and rapid evolution of innovation, healthcare funding systems face major challenges in four areas:

1. Affordability, which will result in an increasing proportion of healthcare cost being shifted to patients
2. Assessment of value, on which to base rational allocation of limited healthcare budgets
3. Timing of payment, for high-price density products, such as CAR-Ts and gene therapies characterized by high upfront, often one-off, costs
4. Monetization of new approaches, such as digital health

Example: Digital health

The challenges for digital health, in particular, are characterized by systemic hurdles:

- Current payment systems reflect the episodic nature of healthcare (i.e. payment tied to an event or an "encounter")
- For digital health operating outside of "encounters," a lack of reimbursement mechanism for user or manufacturer is a significant barrier to uptake
- Without a clear path to monetization, investment in digital health will be stunted and wither
- There are no (financial) incentives to use transmitted (real-time) data
- Digital health generates data that is not (yet) coordinated or integrated with physician decision-making and disease management

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Disruptor #3: Inadequacy of funding & payment systems

Case study: Gene therapy

Cost is the biggest concern

The cost of these therapies can be extremely expensive and present a large burden to the healthcare system, in the range of $400,000 to $850,000 at the high end, and could be amplified depending on the size of the patient population. A further challenge is the timing of the cost – the fact that all or most of the costs are upfront, not borne over time as with chronic treatment.

Uncertainty around long-term benefit

The pathway to approval of gene therapies, especially if expedited, may yield shorter-term data on efficacy than what is needed to prove the long-term benefits of the therapy. This results in considerable uncertainty around how long the therapeutic benefit of the gene therapy will last and whether a single administration will be sufficient to provide that elusive cure. This impacts payers' willingness to pay, and ability to pay limited by the "traditional" model of short-term budgets.

The challenge of defining value

Payers may have to incorporate measurements of value to patients, the healthcare system and society in their standard value assessments, beyond what they normally evaluate: the health gain for the patient and net direct costs to the healthcare system. Some additional metrics of value to consider for gene therapy include: disease severity, age of disease onset, lifetime burden of the illness – and informal care elements, such as: returning to work or study, increases in productivity and reductions in burden of care for family members. Many payers may be resistant to the idea of pricing and reimbursement being tied to these measurements, which are novel compared with the offset of the medical cost.

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Disruptor #3: Inadequacy of funding & payment systems

Changing funding flows to relieve financial pressure

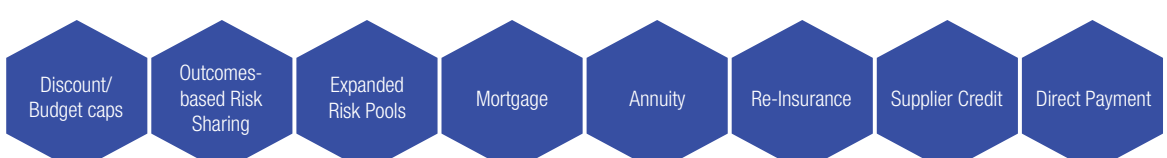
Gene therapies create significant administrative and financial pressures for providers.

Billing and coding issues can be burdensome and complex – and can cause significant delays for the patient.

Payers encounter additional financial pressure in the form of mark-ups from hospitals or specialized treatment centres, which can be a percentage of the payment in addition to the cost of the therapy itself. One option is for payers to purchase the gene therapies directly from the manufacturer or pay the manufacturer directly, to avoid the mark up.

Payment options for gene therapies

Traditional financing mechanisms to pay for pharmaceuticals are not adequate for gene therapies. Alternative payment models, more common to the financial services sector, are being considered:



Any one, or combination, of these models have the potential to incentivize payers to invest in a gene therapy that may produce a better health outcome and lower cost over time, as opposed to paying for a competing product that is repeatedly administered, with higher long-term costs – or even with a larger one-time/upfront cost for a curative therapy.

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Enabler #1: Anticipating the future – Dynamic Market Simulation (DMS)

Any company playing in this dynamic, rapidly changing environment needs to gain market foresight into how the landscape may evolve in the future and the consequences of this for their R&D and commercial decision making.

It is critically important to understand the inter-play and dynamics between the various stakeholders:

- How physicians will make prescribing decisions
- How payers will assess products, approach pricing and control access
- The interaction of competing (intra- and inter-company) strategies
- The implications of alternative decisions for future commercial success
- How the competing companies will differentiate themselves and most effectively co-position their assets to maximise potential
- Geographical differences: How patients of different cultural and social background interpret value in health and contribute to disease management

You cannot predict the unpredictable, but you can learn from it.

Ipsos recommends using an experiential approach to market foresight, called Dynamic Market Simulation (DMS), sometimes called competitive simulation or war gaming. Ipsos has considerable experience in running such exercises, having developed and facilitated over 20 such exercises in various disease area in the past two years.

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Enabler #1: Anticipating the future – DMS – How do we do it?

Development a winning culture of capabilities: Through participation in competitive simulation workshops, based on a foundation of strong insight and incorporation of real-world variables.

Best-in-class methodology: The interaction of the strategies of competing players. The incorporation of payers and physicians into the simulation as both advisers and decision-makers. The linking of price, access, positioning and uptake with brand strategy (evidence development and commercial strategies).

Multiple modules used to simulate the competitive battle over several years: Each module of the workshop focuses on the development and commercial decisions in a specific year. Over a period of one to two days, the workshop simulates a three- to five-year time period in the battle between the competing companies, their products and their dynamic interaction.

Simple and transparent market dynamics: Focusing on market dynamics, the uncertainty surrounding outcomes data and the drivers of internal and external decision-making processes allows different criteria to be explored and powerful lessons learned in advance.

Tracking Key Performance Indicators (KPIs): A simple and transparent semi-quantitative model is used in the background to track the relative performance of all the players, comparing this with company specific KPIs.

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Enabler #2: Removing the barriers

Anticipating the future will identify many opportunities and threats for a company, with barriers to success falling into two types:

Regulatory barriers

- Regulatory systems
- Health Technology Assessment (HTA) systems
- Coding, payment and funding systems

Stakeholder barriers

- Payer & patient willingness to pay
- Physician & patient willingness to use
- New roles of patient, physician & data in disease management

Insight from Ipsos' Dynamic Market Simulation (DMS) experience indicates there is a common dominant critical success factor for overcoming these barriers and delivering sustainable win-win outcomes – Collaboration. Specifically:

- Collaboration with competitors
- Collaboration between the pharma/biologics industry and other stakeholders (policymakers, payers, patients, physicians)
- Collaboration that avoids overt single-stakeholder competitive advantage

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Enabler #3: Winning differentiation

Once the future has been anticipated and the barriers have been removed, all that remains is winning and to continue winning: Sustainable competitive advantage.

Insight from Ipsos' Dynamic Market Simulation (DMS) experience indicates there is a common dominant critical success factor for winning: Differentiation.

Differentiation along the entire value chain is a critical success factor for sustainable differentiation

Clinical development and regulatory	Market access	Manufacturing costs	Sales and marketing
Clinical success and speed to market	Build trust and network development	Optimize supply chain and manufacturing	Branded mentality to drive adoption

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Enabler #3: Winning differentiation

In the disrupted healthcare environment of the future, it will no longer be sufficient to:

- Develop and manufacture a pill
- Sell it at a single monthly price
- Register and promote it on the basis of randomised clinical trials (RCTs)
- Maintain data ownership and exclusivity
- Do all of the above independently

Ipsos research indicates there are four pillars of winning differentiation:

Product proposition	Pricing/Value proposition	Evidence	Capabilities
How will the product itself be differentiated?	How will the product differ from the competition in terms of price and value?	Beyond efficacy and safety...	Planning and timing; working with partners
Innovative “product plus solutions” required”	Innovative “pricing and access solutions” required	How is evidence generation going to differ from other products?	Corporate and product image, reputation, track record

In delivering winning differentiation, getting the right balance between in-house and strategic alliances will be key to future commercial success.

The future of market access: Three disruptors & three enablers

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The future will see three types of DISRUPTIONS:

- Science and technology
- Assessment and evidence
- Funding and payment

Successful future delivery of value and market access will be ENABLED by:

- Anticipating the future
- Removing the barriers
- Establishing winning differentiation

Let's start the conversation!

Reach out to your Ipsos account contact or our Evidence, Access and Value leaders:

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Ipsos' Healthcare Service Line partners with pharmaceutical, biotech and medical device manufacturers to inspire better healthcare. Operating in 50+ markets, our 1,000+ experts support key business decisions for our clients throughout the commercial lifecycle, from early-stage strategy, to launch, to performance optimization. We do this through a uniquely integrated combination of therapeutic and market expertise, gold standard real-world evidence and market-leading custom research approaches – all underpinned by a global footprint and unprecedented access to today's healthcare stakeholders.

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