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Financing and Reimbursement of Cures in the US

Implications for employer stop-loss coverage

MIT CENTER FOR BIOMEDICAL INNOVATION

Implications for employer stop-loss coverage

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Cell and Gene Therapies Create Volatility for Self-Insured Employers

Self-Insured employers will assume the actuarial risk of cell and gene therapies

Many will mitigate this risk using stop-loss insurance

Actuarial Risk

- Severity risk: high cost claims ranging from $1M and above per occurrence
- Frequency risk: having multiple high cost claimants

Purpose of Stop-loss Insurance for Self-Insured Employers

- **Smaller employers (less than 1,000 employees) typically purchase <u>individual</u> and <u>aggregate</u> coverages**
  - Individual protects from catastrophic claims on a “per claimant” basis (i.e. severity risk)
  - Aggregate protects from having too many high cost claims in total (i.e. frequency risk)
    - Referred to as “budget insurance”, aggregate coverage is typically provided as a multiple of expected claims (most commonly at 125% of expected but can offered as low as 110% of expected)

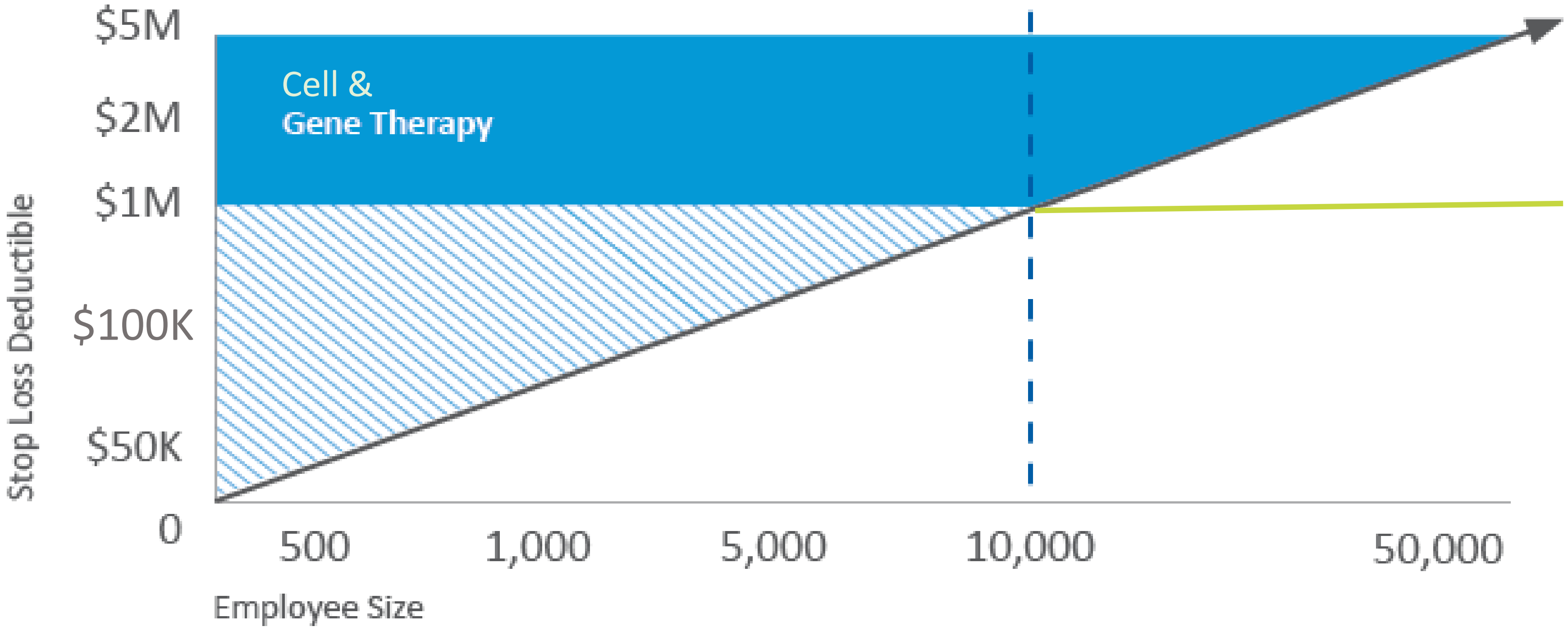
- **As employer size increases – severity and frequency risk can be absorbed by the employer**
  - Larger employers will purchase higher deductibles and assume more self-insured risk
    - Increasing deductibles: $90K – $125K per 1,000 employees
  - Above 1,000 employees the use of aggregate coverage is less frequent due to law of large numbers

Stop-loss Marketplace

- $25B industry
  - Market doubled since 2014 (full implementation of Affordable Care Act)
  - Growth of self-insured market
- Carriers providing coverage
  - Large national health insurers (Anthem, Aetna, Cigna, United)
  - Regional health insurers (BCBS plans, Harvard Pilgrim Health Care / Tufts)
  - Specialty life insurers (Sun Life, HCC Life, Gerber Life, Symetra)
  - Property/Casualty (Zurich, Berkley, Swiss Re)

Stop-loss Insurance is Less Prevalent for Larger Employers

Traditional higher-deductible stop loss insurance doesn't offer financial protection from FDA-approved gene therapies.



Issue #1: Known vs Unknown Claims

Stop-loss insurance is meant to protect from unknown claims

- Spinal muscular atrophy identified during pregnancy where infant needs spinzara or zolgensma will be covered as an unknown claim
- An infant currently using spinraza and who has the potential for use of zolgensma may be considered a known claim and could be excluded from coverage (“lasering is a term used in stop-loss and is meant to exclude individuals from coverage)
- Hemophilia patient currently using factor medication would be considered a known claimant

Issue #1: Known vs Unknown Claims

Known claims

- Patient using Humira or other ongoing maintenance medications (e.g. hemophilia)
- Patient on an organ donor waitlist
- Annuitized payments for gene therapy

Unknown claims

- Hospitalizations
- New drug therapies including CGT

Life: Smoker vs non-smoker
Auto: speeding tickets vs safe driver
Cyber: history of breaches vs no breach
Mal-Practice: history of lawsuits vs no record

Issue #2: Misalignment between employer, stop-loss insurer, and reinsurer

Employers will need sound medical policy regarding use of CGTs and will need confirmation from stop-loss insurer that they are in agreement

- Stop-loss insurance policies will have terms/conditions and potentially claim exclusions that could create a gap in coverage for an employer
  - Common for employer to ask for "plan mirroring"
  - Focus on quality and highly rated carriers
- Many stop-loss insurers will mitigate their exposure by purchasing reinsurance and reinsurers similarly will have terms/conditions and potentially claim exclusions creating a gap between stop-loss carrier and reinsurer
  - Common for reinsurers to exclude gene therapy coverage to mitigate risk

Issue #3: Jumbo employers do not purchase stop-loss insurance

Jumbo employers (10,000+) who do not purchase stop-loss face a frequency risk from CGTs that traditional stop loss doesn't fix for them

- Higher deductibles ($2M and above) will not mitigate frequency risk from CGTs
  - Aggregate coverage for jumbo employers is not cost effective
- With most CGTs ranging from $500K to $2M, CGTs pose more frequency risk than severity risk for jumbo employers
- Jumbo employers prefer to **budget** (100% self-insured) for expenses as opposed to spending **fixed** costs on insurance
  - Low frequency / high severity CGTs will be hard to budget for due to volatility

Issue #4: Durability and Subrogation

Gene therapies that are not durable may have future warranty claims

- Stop-loss insurers will want ability to track patients into the future to confirm durability of treatments
    - Most policies will have a subrogation clause allowing insurer to recoup reimbursements in the event that losses are no longer losses (i.e. manufacturer returns dollars for lack of durability)
- Mobility of patients, insurers, employers, broker/consultants will make future tracking difficult
- Stop-loss insurers will either develop capabilities to track or will need to work with vendors who have such capabilities

Summary

- Stop-loss insurance will provide coverage from CGTs in most cases and for most employers
  - Known claimants may be excluded from coverage
  - Large/jumbo employers who do not purchase some level of stop-loss coverage will assume frequency risk of CGTs
- For those who purchase stop-loss insurance, a one-time expense may be more beneficial than annuitized payments
- Employers, stop-loss insurers and reinsurers will need alignment on criteria for coverage