The New ASOP 56 on Modeling: An Overview and A Timely Pharmacy Case Study

Kristi Bohn, Tom Dow, Rebecca Owen

October 28, 2020
ACTIVE PARTICIPATION IN THE SOCIETY OF ACTUARIES IS AN IMPORTANT ASPECT OF MEMBERSHIP. WHILE THE POSITIVE CONTRIBUTIONS OF PROFESSIONAL SOCIETIES AND ASSOCIATIONS ARE WELL-RECOGNIZED AND ENCOURAGED, ASSOCIATION ACTIVITIES ARE VULNERABLE TO CLOSE ANTITRUST SCRUTINY. BY THEIR VERY NATURE, ASSOCIATIONS BRING TOGETHER INDUSTRY COMPETITORS AND OTHER MARKET PARTICIPANTS.

ANTITRUST COMPILANCE GUIDELINES

Active participation in the Society of Actuaries is an important aspect of membership. While the positive contributions of professional societies and associations are well-recognized and encouraged, association activities are vulnerable to close antitrust scrutiny. By their very nature, associations bring together industry competitors and other market participants.

The United States antitrust laws aim to protect consumers by preserving the free economy and prohibiting anti-competitive business practices; they promote competition. There are both state and federal antitrust laws, although state antitrust laws closely follow federal law. The Sherman Act, is the primary U.S. antitrust law pertaining to association activities. The Sherman Act prohibits every contract, combination or conspiracy that places an unreasonable restraint on trade. There are, however, some activities that are illegal under all circumstances, such as price fixing, market allocation and collusive bidding.

There is no safe harbor under the antitrust law for professional association activities. Therefore, association meeting participants should refrain from discussing any activity that could potentially be construed as having an anti-competitive effect. Discussions relating to product or service pricing, market allocations, membership restrictions, product standardization or other conditions on trade could arguably be perceived as a restraint on trade and may expose the SOA and its members to antitrust enforcement procedures.

While participating in all SOA in person meetings, webinars, teleconferences or side discussions, you should avoid discussing competitively sensitive information with competitors and follow these guidelines:

- **Do not** discuss prices for services or products or anything else that might affect prices
- **Do not** discuss what you or other entities plan to do in a particular geographic or product markets or with particular customers.
- **Do not** speak on behalf of the SOA or any of its committees unless specifically authorized to do so.
- **Do** leave a meeting where any anticompetitive pricing or market allocation discussion occurs.
- **Do** alert SOA staff and/or legal counsel to any concerning discussions
- **Do** consult with legal counsel before raising any matter or making a statement that may involve competitively sensitive information.

Adherence to these guidelines involves not only avoidance of antitrust violations, but avoidance of behavior which might be so construed. These guidelines only provide an overview of prohibited activities. SOA legal counsel reviews meeting agenda and materials as deemed appropriate and any discussion that departs from the formal agenda should be scrutinized carefully. Antitrust compliance is everyone’s responsibility; however, please seek legal counsel if you have any questions or concerns.
Presentation Disclaimer

Presentations are intended for educational purposes only and do not replace independent professional judgment. Statements of fact and opinions expressed are those of the participants individually and, unless expressly stated to the contrary, are not the opinion or position of the Society of Actuaries, its cosponsors or its committees. The Society of Actuaries does not endorse or approve, and assumes no responsibility for, the content, accuracy or completeness of the information presented. Attendees should note that the sessions are audio-recorded and may be published in various media, including print, audio and video formats without further notice.
Our Panel

• Tom Dow
• Rebecca Owen
• Kristi Bohn
An Overview of ASOP 56: Modeling

• Effective October 1, 2020

• Purpose: This actuarial standard of practice provides guidance to actuaries when performing actuarial services with respect to designing, developing, selecting, modifying, using, reviewing, or evaluating models.

• Model: A simplified representation of relationships among real world variables, entities, or events using statistical, financial, economic, mathematical, non-quantitative, or scientific concepts and equations. A model consists of three components:
  • an information input component, which delivers data and assumptions to the model;
  • a processing component, which transforms input into output;
  • and a results component, which translates the output into useful business information.
Sickle Cell Disease: A Brief Overview

• Sickle Cell Disease (SCD) is an umbrella term used for a group of inherited blood disorders, the most common being sickle cell anemia.
• Came primarily from Africa, but also indigenous to India and the Middle East.
• Manifests at about 6-8 months old.
• Severity of symptoms varies from person to person and is often episodic.
• Sickle Cell crises are marked by excruciating pain.
• Splenic crises are particularly severe and can be fatal.
Geographic Variation in the Number of Medicaid and CHIP Beneficiaries with SCD Per 100,000 Beneficiaries in 2017

National prevalence of 74 per 100,000 beneficiaries

Prevalence by state:
- 0-49
- 50-99
- 100-149
- 150-249

Where beneficiaries with SCD live:
- 91% Urban
- 9% Rural
Sickle Cell: A Brief Overview

What is sickle cell disease?

Sickle cell disease (SCD) is a group of autosomal recessive disorders caused by a mutation in the HBB gene. This mutation affects the patient’s hemoglobin which delivers oxygen to the body’s cells. The abnormal hemoglobin (aka hemoglobin S) become rigid and sticky and are shaped like sickle or crescent moons.

The irregularly shaped cells can get stuck in small blood vessels and slow or block blood flow and oxygen to other parts of the body causing anemia, infections, and periodic episodes of pain.

Who is affected?

According to the US Centers for Disease Control and Prevention, the exact number of individuals with SCD in the US is unknown. It is estimated that SCD affects approximately 100,000 Americans, about 1 out of every 365 Black or African American births, and 1 out of every 16,300 Hispanic American births.

Despite routine screening performed on a baby after they’re born, about 31% of infants did not receive long-term follow-up after diagnosis.

Sickle Cell: A Brief Overview

Treatment

Although there are several treatments available to mask the symptoms or slow the progression of the disease only an allogeneic bone marrow transplant from a matched donor is a potential cure for SCD. Less than one-third of people with SCD can find a matched donor.

Provider Challenges

Access to care is a significant challenge for most patients. Much of this can be attributed to their day to day and QOL challenges. The daily challenges for SCD patients often makes it difficult to find and maintain a job which is a possible cause for the disproportionate amount of SCD patients covered under Medicaid.

The State of Sickle Cell Disease: 2016 Report, written in collaboration between the American Society of Hematology (ASH) and other groups, outlines variances in medical care and opportunities for research into new treatments.
Modeling Approach when Historic Data Not Available

Probability of FDA Approval in Contract Year
Adjustments for Timing of FDA Approval within Contract Year
Adjustment for Age Indication
Condition Prevalence
Probability of Use
Annual Cost if Treated
Benefit Design Impacts
Premium Impact PEPM or PMPM

Adjust for monthly rates
Adjust if family rates
Desired Loss Ratio

3.6 Evaluation and Mitigation of Model Risk, appropriate degree may depend on...
Model’s intended purpose
Nature, complexity of the model
Operating environment, governance, controls
Changes
Balance cost w/ potential model risk
Modeling Assumption Considerations

Life or death?
Study Findings (clinical trial submissions, media, conferences)
Competing alternative treatments available, other clinical trials
Outcome of European approval
Political / lobby pressure

3.1.6 Assumptions Used As Input
Range of Assumptions
Consistency
Appropriateness of Input in
Current Model Run
Modeling Assumption Considerations

Partial year availability? Manufactured at risk?
COVID impact? Delay coverage due to insurer’s P&T activities? Role of fast-tracked FDA approval on insurers’ acceptance Affected patient and provider readiness, knowledge, and attitudes
Pre-treatment regimen time requirements

Probability of FDA Approval in Contract Year
Adjustments for Timing of FDA Approval within Contract Year
Adjustment for Age Indication
Condition Prevalence
Probability of Use
Annual Cost if Treated
Benefit Design Impacts
Premium Impact PEPM or PMPM
Adjust for monthly rates
Adjust if family rates
Desired Loss Ratio

Section 4. Communications and Disclosures
4.1 Required Disclosures in an Actuarial Report
ASOP Nos. 23 and 41
Modeling Assumption Considerations

- Probability of FDA Approval in Contract Year
- Adjustments for Timing of FDA Approval within Contract Year
- Adjustment for Age Indication
- Condition Prevalence
- Probability of Use
- Annual Cost if Treated
- Benefit Design Impacts
- Premium Impact PEMP or PMPM
- Adjust for monthly rates
- Adjust if family rates
- Desired Loss Ratio
- Age xx and older? Age xx and younger?
- Market-specific age distribution (Medicare, Medicaid, Commercial, Student)
- Condition-specific mortality?

3.1.5 Data
Appropriate data for model’s intended purpose
ASOP 23
Modeling Assumption Considerations

Data Sources: CDC, NIH, CMS, KFF, Condition-based organizations
Market-specific prevalence effects (Medicare, Medicaid, Commercial, Student)
Credibility of group’s data (ICD 10, prior services and treatments, disclosure for stop loss/ reinsurance)
Condition-specific mortality geography (rural/suburban/metro)

3.6.1 Model Testing
Reconciling inputs w. data sources documenting differences
Checking formulas, logic, etc.
Testing key assumptions could involve sensitivity testing
Reconciling output from prior runs
Modeling Assumption Considerations

- Probability of FDA Approval in Contract Year
- Adjustments for Timing of FDA Approval within Contract Year
- Adjustment for Age Indication
- Condition Prevalence
- Probability of Use in Contract Year
- Annual Cost if Treated
- Benefit Design Impacts
- Premium Impact PEPM or PMPM

3.5 Reliance on Experts
3.3 Reliance on Data ...Supplied by Others
3.4 Reliance on Models Developed by Others
4.2 Additional Disclosures in an Actuarial Report

- Alternative treatments available
- Burden of pre- and post-treatment regimen
- Excluded Coverage
- Cost, safety concerns
- Probability of an inhibitor to vector
- Care management techniques (step therapy, prior auth)
- Life or death? Will some wait and see?
- Role of stop loss / reinsurance in coverage and care management decisions
- Provider training / availability
- Patient and provider attitudes and awareness
Modeling Assumption Considerations

3.2 Understanding the Model
Basic Operations    Time constraints
Important Dependencies
Major sensitivities  Practical considerations
Known weaknesses in assumptions
Known weaknesses in methods
Known material limitations on model, data
Modeling Assumption Considerations

- Probability of FDA Approval in Contract Year
- Adjustments for Timing of FDA Approval within Contract Year
- Adjustment for Age Indication
- Condition Prevalence
- Probability of Use
- Annual Cost if Treated
- Benefit Design Impacts
- Deductible, Coinsurance, Limits
- Leveraging effect on stop loss and reinsurance

2.12 Overfitting

3.1.4 Model Structure
Specific to business segment, contract, or plan
Form of model
Risk of overfitting?
Can the model appropriately represent options
Modeling Assumption Considerations

3.1.6 e. Reasonable Model in the Aggregate
3.6.2 Model Output Validation
3.6.3 Review by Another Professional
3.6.4 Reasonable Governance and Controls
3.6.5 Mitigating Misuse and Misinterpretation
3.7 Documentation

Profit / risk margin
commissions
premium tax
admin costs
Risk-adjusted return on capital
Sickle Cell: Current Treatments

- Folic acid (vitamin B-9)
- Penicillin
- Hydroxyurea:
  - increases hemoglobin F, now generic, approved in 1998, costs app. $1,000 per year
- Recent Approvals
  - Oxbryta (voxelotor), a daily pill, inhibits hemoglobin S polymerization and subsequent red blood cell (RBC) sickling, app. $100,000 per year, approved Nov. 25, 2019
  - Adakveo (crizanlizumab): Selectin blocker infused once per month and approved by the FDA On Nov. 15, 2019, app. $88,000 per year, for prevention of recurrent vaso-occlusive crises (VOCs), pain crises
  - Endari is taken twice-daily, approved July 7, 2017, improves red blood cells flexibility, app. $88,000
- Blood Transfusions
  - high rates of alloimmunization
  - High rates of iron overload, commonly treated with iron chelation
- Stem cell transplantation
- Pain Management: Opioids, narcotics, ketorolac

Blood Transfusions
- high rates of alloimmunization
- High rates of iron overload, commonly treated with iron chelation
Sickle Cell: Milliman Study

Sickle Cell Pipeline: Possible Future Treatments

- **Gene Therapy / Gene Editing**
  - LentiGlobin, HGB-210, NCT02140554
  - CRISPR/Cas12a (aka Cpf1), EDIT-301
  - OTQ923, NCT04443907
  - HIX763, NCT04443907
  - ARU-1801, NCT02186418
  - CRISPR/Cas 9, CTX001, NCT03745287
  - BIVV003, NCT03653247
  - BCL11A shRNA (mir), NCT03282656

- **PKR Activators**
  - Mitapivat, AG-348, NCT04000165
  - FT-4202, NCT03815695

- **Inhibitors**
  - IMR-687, NCT03401112, NCT04053803

- **Pain Management and Blood Flow Improvers**
  - Imatinib, NCT03997903 (pain)
  - Olinciguat, IW-1701, NCT03285178 (promotes blood flow)
  - Rivipansel, GMI-1070, NCT02187003 (prevents vaso-occl)
SCD trials we’re monitoring

Source: Emergingtherapies.com
What is the probability that a 100,000 life group will see cell and gene cases in 2021?

- 100,000 life groups should expect to see 0-7 cases in 2022 at minimum

- With prices of $850K and $3M (Potential for Roctavian to treat hemophilia) the industry needs management, policy, medical management, and most importantly scale to meet the need of managing these rare conditions.

- The variation in SCD is extremely difficult to price at lower volumes. Reinsurance and Stop Loss innovation can come in to fill the gap but at low membership these therapies alone will be difficult to price

How does this impact my plan? (100K Life Plan)
Sickle Cell: Possible Future Financial Scenarios

First dollar impact of a gene therapy for SCD could have as much as a $2.50 PMPM impact on premiums

<table>
<thead>
<tr>
<th>Medicaid</th>
<th>Commercial</th>
</tr>
</thead>
<tbody>
<tr>
<td>Qualify for Gene Therapy</td>
<td>10%</td>
</tr>
<tr>
<td>Uptake on Gene Therapy</td>
<td>30%</td>
</tr>
<tr>
<td>Cost for the Therapy</td>
<td>$777,000</td>
</tr>
</tbody>
</table>

**Total Addressable Population**
- Medicaid: $351,011,269
- Commercial: $185,720,248
Sickle Cell: Helpful Links and Resources

- Sickle Cell Disease Association of America, Inc. https://www.sicklecelldisease.org
- Seattle Children’s Sickle Cell Program https://www.seattlechildrens.org/clinics/cancer/services/sickle-cell-program
- Sickle Cell Disease News, BioNews Services, LLC: https://sicklecellanemianews.com/
- Wailoo, Keith, UNC Press Books, Dying in the city of the blues: sickle cell anemia and the politics of race and health, 2014
Sickle Cell Pipeline: Helpful Links and Resources

- agios clinical trial and pipeline information, Mitapivat, [https://www.agios.com/pipeline/clinical-programs/](https://www.agios.com/pipeline/clinical-programs/)
- Seethal Jacob, MD, MS, Indiana University, Purdue University, and Children’s Hospital Medical Center, Cincinnati, *Imatinib for Pain in Sickle Cell Anemia (IMPACT)*, clinical trial first posted June 25, 2019, last updated February 12, 2020, [https://clinicaltrials.gov/ct2/show/NCT03997903](https://clinicaltrials.gov/ct2/show/NCT03997903)
Sickle Cell Pipeline: Helpful Links and Resources


2020 VIRTUAL ANNUAL MEETING & EXHIBIT